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By the Committee on Health Regulation; and Senator Gaetz

588-03223-12 20121316c1 A bill to be entitled

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

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

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physical examination if the agency questions the appropriateness of the resident's placement in that facility; authorizing release of the results of the examination to a medical review team to be used along with additional information to determine whether the resident's placement in the assisted living facility is appropriate; providing for resident notification and relocation if the resident's continued placement in the facility is not appropriate; authorizing the agency to require the evaluation of a mental health resident by a mental health professional; authorizing an assisted living facility to discharge a resident who requires more services or care than the facility is able to provide; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; amending s. 456.036, F.S.; providing that all persons who were denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., may regain licensure, certification, or registration only by completing the application process for initial licensure; providing an exception; amending s. 456.074, F.S.; revising the federal offenses for which the Department of Health must issue an emergency order suspending the license of certain health care professionals; amending ss. 458.309 and 459.005, F.S.;

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requiring a physician or osteopathic physician who performs certain medical procedures relating to liposuction in an office setting to register the office with the Department of Health unless that office is licensed as a facility under ch. 395, F.S., relating to hospital licensing and regulation; amending s. 463.002, F.S.; conforming provisions to changes made by the act; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules for the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; authorizing certified optometrists to administer and prescribe pharmaceutical agents under certain circumstances; requiring that a certified optometrist complete a course and subsequent examination on general and ocular pharmacology; providing requirements for the course; requiring that the Florida Medical Association and the Florida Optometric Association jointly develop and administer the course and examination; revising qualifications of certain members of the formulary committee; providing for a formulary of topical ocular pharmaceutical agents which the committee may modify; specifying the agents that make up the statutory formulary of oral pharmaceutical agents; authorizing the deletion of an oral pharmaceutical agent listed in the statutory formulary under certain circumstances; prohibiting the board, the Department of Health, or the State Surgeon General from deleting an oral pharmaceutical agent

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listed in the statutory formulary; amending ss. 463.0057 and 463.006, F.S.; conforming provisions to changes made by the act; amending s. 463.0135, F.S.; requiring that a certified optometrist administer and prescribe oral ocular pharmaceutical agents in a certain manner; requiring that a licensed practitioner who diagnoses a patient who has a neovascular form of glaucoma or progressive glaucoma immediately refer the patient to a physician who is skilled in the diseases of the eye; requiring that comanagement of postoperative care be conducted pursuant to an established protocol; requiring that the patient be informed that a physician will be available for emergency care throughout the postoperative period; requiring that the patient consent in writing to the comanagement relationship; amending s. 463.014, F.S.; revising certain prohibited acts regarding an optometrist conducting surgery and dispensing, administering, ordering, supplying, or selling certain drugs; creating s. 463.0141, F.S.; requiring that adverse incidents in the practice of optometry be reported to the Department of Health; providing requirements for notifying the department of an adverse incident; providing a definition; requiring that the department review each incident and determine whether it involved conduct that is subject to disciplinary action; requiring that the Board of Optometry take disciplinary action if necessary; amending s. 483.035, F.S., relating to licensure and

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regulation of clinical laboratories operated by practitioners for exclusive use; providing applicability to clinical laboratories operated by practitioners licensed to practice optometry; amending s. 483.041, F.S.; revising the definition of the term "licensed practitioner" to include a practitioner licensed under ch. 463, F.S.; amending s. 483.181, F.S.; requiring clinical laboratories to accept human specimens submitted by practitioners licensed to practice under ch. 463, F.S.; amending s. 499.003, F.S.; removing a requirement that a contract provider or subcontractor maintain prescription drugs of the agency or entity in its possession separate and apart from other prescription drugs; amending s. 766.102, F.S.; providing that the claimant has the burden of proving by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests; amending s. 766.106, F.S.; authorizing a prospective defendant to obtain informal discovery by conducting ex parte interviews of treating health care providers; requiring advance notice to the claimant of an ex parte interview; creating s. 766.1091, F.S.; authorizing a health care provider or health care clinic and a patient to agree to submit a claim of

medical negligence to arbitration; requiring that the arbitration agreement be governed by ch. 682, F.S.; authorizing the arbitration agreement to contain a provision that limits an award of damages; amending s. 893.02, F.S.; revising the definition of the term "practitioner" to include certified optometrists for purposes of the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 893.05, F.S.; prohibiting certified optometrists from administering and prescribing certain controlled substances; requiring the Agency for Health Care Administration to prepare a report for public comment and submission to the Legislature following the expansion of services to new populations or of new services; providing effective dates.

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

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

(1) "Accrediting organizations" means national

395.002 Definitions.—As used in this chapter:

accreditation organizations that are approved by the Centers for
Medicare and Medicaid Services and whose standards incorporate
comparable licensure regulations required by the state the Joint
Commission on Accreditation of Healthcare Organizations, the

201 American Osteopathic Association, the Commission on

202 Accreditation of Rehabilitation Facilities, and the

Accreditation Association for Ambulatory Health Care, Inc.

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

- 400.474 Administrative penalties.-
- (6) The agency may deny, revoke, or suspend the license of a home health agency and shall impose a fine of \$5,000 against a home health agency that:
 - (a) Gives remuneration for staffing services to:
- 1. Another home health agency with which it has formal or informal patient-referral transactions or arrangements; or
- 2. A health services pool with which it has formal or informal patient-referral transactions or arrangements,

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

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

233 market value remuneration.

- (c) Provides staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.
- (d) Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within 5 years before the request.
- (e) Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395, chapter 429, or this chapter from whom the home health agency receives referrals.
- (f) Fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:
- 1. The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency;
- 2. The number of patients receiving both home health services from the home health agency and hospice services;
- 3. The number of patients receiving home health services from that home health agency; and
- 4. The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of \$25,000 during the calendar quarter.
- $\underline{\text{(f)}}$ Gives cash, or its equivalent, to a Medicare or Medicaid beneficiary.

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

- (h)(i) Gives remuneration to a physician without a medical director contract being in effect. The contract must:
 - 1. Be in writing and signed by both parties;
- 2. Provide for remuneration that is at fair market value for an hourly rate, which must be supported by invoices submitted by the medical director describing the work performed, the dates on which that work was performed, and the duration of that work; and
 - 3. Be for a term of at least 1 year.

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

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(i) (j) Gives remuneration to:

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1. A physician, and the home health agency is in violation of paragraph (g) $\frac{h}{h}$ or paragraph (h) $\frac{h}{h}$;

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A member of the physician's office staff; or
 An immediate family member of the physician,

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

291 staff.

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

 $\underline{(k)}$ (1) Demonstrates a pattern of billing the Medicaid program for services to Medicaid recipients which are medically unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically unnecessary services within one Medicaid program integrity audit period.

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

- (7) The agency shall impose a fine of \$50 per day against a home health agency that fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:
- (a) The number of patients receiving both home health services from the home health agency and hospice services;
- (b) The number of patients receiving home health services from the home health agency;
- (c) The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency; and

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

Section 3. Paragraph (1) 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:
- (1) Orthotic, or prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.
- (m) Entities that are owned or controlled, directly or indirectly, by a publicly traded entity that has \$100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care practitioners who are employed or contracted by an entity described in this paragraph.

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

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

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

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

378 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 $\underline{6}$ a $\underline{9}$ period of $\underline{5}$ years to satisfy all necessary inquiries by the agency.
- (k) Report a change in any principal of the provider, including any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider, to the agency in writing no later than 30 days after the change occurs.
- (6) A Medicaid provider agreement may be revoked, at the option of the agency, <u>due to</u> as the result of a change of ownership of any facility, association, partnership, or other entity named as the provider in the provider agreement.
- (a) In the event of a change of ownership, the transferor remains liable for all outstanding overpayments, administrative fines, and any other moneys owed to the agency before the effective date of the change of ownership. In addition to the continuing liability of the transferor, The transferee is also liable to the agency for all outstanding overpayments identified by the agency on or before the effective date of the change of ownership. For purposes of this subsection, the term "outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of the change of ownership. In the event of a change of ownership for a skilled nursing

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

(b) At least 60 days before the anticipated date of the change of ownership, the transferor must shall notify the agency of the intended change of ownership and the transferee must shall submit to the agency a Medicaid provider enrollment application. If a change of ownership occurs without compliance with the notice requirements of this subsection, the transferor and transferee are shall be jointly and severally liable for all overpayments, administrative fines, and other moneys due to the agency, regardless of whether the agency identified the overpayments, administrative fines, or other moneys before or after the effective date of the change of ownership. The agency may not approve a transferee's Medicaid provider enrollment application if the transferee or transferor has not paid or agreed in writing to a payment plan for all outstanding overpayments, administrative fines, and other moneys due to the agency. This subsection does not preclude the agency from seeking any other legal or equitable remedies available to the agency for the recovery of moneys owed to the Medicaid program. In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative

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fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179 if the Medicaid provider enrollment application for change of ownership is submitted before the change of ownership.

- (c) As used in this subsection, the term:
- 1. "Administrative fines" includes any amount identified in a notice of a monetary penalty or fine which has been issued by the agency or other regulatory or licensing agency that governs the provider.
- 2. "Outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of a change of ownership.
- (7) The agency may require, As a condition of participating in the Medicaid program and before entering into the provider agreement, the agency may require that the provider to submit information, in an initial and any required renewal applications, concerning the professional, business, and personal background of the provider and permit an onsite inspection of the provider's service location by agency staff or other personnel designated by the agency to perform this function. Before entering into a provider agreement, the agency may shall perform an a random onsite inspection, within 60 days after receipt of a fully complete new provider's application, of the provider's service location prior to making its first payment to the provider for Medicaid services to determine the applicant's ability to provide the services in compliance with the Medicaid program and professional regulations that the applicant is proposing to provide for Medicaid reimbursement.

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The agency is not required to perform an onsite inspection of a provider or program that is licensed by the agency, that provides services under waiver programs for home and communitybased services, or that is licensed as a medical foster home by the Department of Children and Family Services. As a continuing condition of participation in the Medicaid program, a provider must shall immediately notify the agency of any current or pending bankruptcy filing. Before entering into the provider agreement, or as a condition of continuing participation in the Medicaid program, the agency may also require that Medicaid providers reimbursed on a fee-for-services basis or fee schedule basis that which is not cost-based, post a surety bond not to exceed \$50,000 or the total amount billed by the provider to the program during the current or most recent calendar year, whichever is greater. For new providers, the amount of the surety bond shall be determined by the agency based on the provider's estimate of its first year's billing. If the provider's billing during the first year exceeds the bond amount, the agency may require the provider to acquire an additional bond equal to the actual billing level of the provider. A provider's bond need shall not exceed \$50,000 if a physician or group of physicians licensed under chapter 458, chapter 459, or chapter 460 has a 50 percent or greater ownership interest in the provider or if the provider is an assisted living facility licensed under chapter 429. The bonds permitted by this section are in addition to the bonds referenced in s. 400.179(2)(d). If the provider is a corporation, partnership, association, or other entity, the agency may require the provider to submit information concerning

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the background of that entity and of any principal of the entity, including any partner or shareholder having an ownership interest in the entity equal to 5 percent or greater, and any treating provider who participates in or intends to participate in Medicaid through the entity. The information must include:

- (a) Proof of holding a valid license or operating certificate, as applicable, if required by the state or local jurisdiction in which the provider is located or if required by the Federal Government.
- (b) Information concerning any prior violation, fine, suspension, termination, or other administrative action taken under the Medicaid laws, rules, or regulations of this state or of any other state or the Federal Government; any prior violation of the laws, rules, or regulations relating to the Medicare program; any prior violation of the rules or regulations of any other public or private insurer; and any prior violation of the laws, rules, or regulations of any regulatory body of this or any other state.
- (c) Full and accurate disclosure of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.
- (d) If a group provider, identification of all members of the group and attestation that all members of the group are enrolled in or have applied to enroll in the Medicaid program.
- (8) (a) Each provider, or each principal of the provider if the provider is a corporation, partnership, association, or

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

(a) Notwithstanding the above, the agency may require a background check for any person reasonably suspected by the agency to have been convicted of a crime. This subsection does

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- 1. A hospital licensed under chapter 395;
- 554 2. A nursing home licensed under chapter 400;
 - 3. A hospice licensed under chapter 400;
 - 4. An assisted living facility licensed under chapter 429;
 - 1.5. A unit of local government, except that requirements of this subsection apply to nongovernmental providers and entities contracting with the local government to provide Medicaid services. The actual cost of the state and national criminal history record checks must be borne by the nongovernmental provider or entity; or
 - 2.6. Any business that derives more than 50 percent of its revenue from the sale of goods to the final consumer, and the business or its controlling parent is required to file a form 10-K or other similar statement with the Securities and Exchange Commission or has a net worth of \$50 million or more.
 - (b) Background screening shall be conducted in accordance with chapter 435 and s. 408.809. The cost of the state and national criminal record check shall be borne by the provider.
 - (c) Proof of compliance with the requirements of level 2 screening under chapter 435 conducted within 12 months before the date the Medicaid provider application is submitted to the agency fulfills the requirements of this subsection.
 - Section 6. Present paragraphs (e) and (f) of subsection (1) of section 409.913, Florida Statutes, are redesignated as paragraphs (f) and (g), respectively, a new paragraph (e) is added to that subsection, and subsections (2), (9), (13), (15), (16), (21), (22), (25), (28), (29), (30), and (31) of that section are amended, to read:

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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

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

- (1) For the purposes of this section, the term:
- (e) "Medicaid provider" or "provider" has the same meaning as provided in s. 409.901 and, for purposes of oversight of the integrity of the Medicaid program, also includes a participant in a Medicaid managed care provider network.
- (2) The agency shall conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and shall report the findings of any overpayments in audit reports as appropriate. At least 5 percent of all audits must

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

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

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a provider is neither curtailed nor limited during a period of litigation between the agency and the provider.

- (13) The agency shall immediately terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, has been convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession, or an offense listed under s. 409.907(10), s. 408.809(4), or s. 435.04(2) has been:
- (a) Convicted of a criminal offense related to the delivery of any health care goods or services, including the performance of management or administrative functions relating to the delivery of health care goods or services;
- (b) Convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession; or
- (c) Found by a court of competent jurisdiction to have neglected or physically abused a patient in connection with the delivery of health care goods or services. If the agency determines that the a provider did not participate or acquiesce in the an offense specified in paragraph (a), paragraph (b), or paragraph (c), termination will not be imposed. If the agency effects a termination under this subsection, the agency shall issue an immediate final order pursuant to s. 120.569(2)(n).
 - (15) The agency shall seek a remedy provided by law,

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including, but not limited to, any remedy provided in subsections (13) and (16) and s. 812.035, if:

- (a) The provider's license has not been renewed, or has been revoked, suspended, or terminated, for cause, by the licensing agency of any state;
- (b) The provider has failed to make available or has refused access to Medicaid-related records to an auditor, investigator, or other authorized employee or agent of the agency, the Attorney General, a state attorney, or the Federal Government;
- (c) The provider has not furnished or has failed to make available such Medicaid-related records as the agency has found necessary to determine whether Medicaid payments are or were due and the amounts thereof;
- (d) The provider has failed to maintain medical records made at the time of service, or prior to service if prior authorization is required, demonstrating the necessity and appropriateness of the goods or services rendered;
- (e) The provider is not in compliance with provisions of Medicaid provider publications that have been adopted by reference as rules in the Florida Administrative Code; with provisions of state or federal laws, rules, or regulations; with provisions of the provider agreement between the agency and the provider; or with certifications found on claim forms or on transmittal forms for electronically submitted claims that are submitted by the provider or authorized representative, as such provisions apply to the Medicaid program;
- (f) The provider or person who ordered, authorized, or prescribed the care, services, or supplies has furnished, or

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ordered, or authorized the furnishing of, goods or services to a recipient which are inappropriate, unnecessary, excessive, or harmful to the recipient or are of inferior quality;

- (g) The provider has demonstrated a pattern of failure to provide goods or services that are medically necessary;
- (h) The provider or an authorized representative of the provider, or a person who ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted false or a pattern of erroneous Medicaid claims;
- (i) The provider or an authorized representative of the provider, or a person who has ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted a Medicaid provider enrollment application, a request for prior authorization for Medicaid services, a drug exception request, or a Medicaid cost report that contains materially false or incorrect information;
- (j) The provider or an authorized representative of the provider has collected from or billed a recipient or a recipient's responsible party improperly for amounts that should not have been so collected or billed by reason of the provider's billing the Medicaid program for the same service;
- (k) The provider or an authorized representative of the provider has included in a cost report costs that are not allowable under a Florida Title XIX reimbursement plan, after the provider or authorized representative had been advised in an audit exit conference or audit report that the costs were not allowable;
- (1) The provider is charged by information or indictment with fraudulent billing practices or any offense referenced in

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<u>subsection (13)</u>. The sanction applied for this reason is limited to suspension of the provider's participation in the Medicaid program for the duration of the indictment unless the provider is found guilty pursuant to the information or indictment;

- (m) The provider or a person who has ordered, authorized, or prescribed the goods or services is found liable for negligent practice resulting in death or injury to the provider's patient;
- (n) The provider fails to demonstrate that it had available during a specific audit or review period sufficient quantities of goods, or sufficient time in the case of services, to support the provider's billings to the Medicaid program;
- (o) The provider has failed to comply with the notice and reporting requirements of s. 409.907;
- (p) The agency has received reliable information of patient abuse or neglect or of any act prohibited by s. 409.920; or
- (q) The provider has failed to comply with an agreed-upon repayment schedule.

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

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

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(a) Suspension for a specific period of time of not more than 1 year. Suspension <u>precludes</u> shall <u>preclude</u> 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 <u>precludes</u> shall <u>preclude</u> participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.
- (c) Imposition of a fine of up to \$5,000 for each violation. Each day that an ongoing violation continues, such as refusing to furnish Medicaid-related records or refusing access to records, is considered, for the purposes of this section, to be a separate violation. Each instance of improper billing of a Medicaid recipient; each instance of including an unallowable cost on a hospital or nursing home Medicaid cost report after the provider or authorized representative has been advised in an audit exit conference or previous audit report of the cost unallowability; each instance of furnishing a Medicaid recipient goods or professional services that are inappropriate or of inferior quality as determined by competent peer judgment; each instance of knowingly submitting a materially false or erroneous Medicaid provider enrollment application, request for prior authorization for Medicaid services, drug exception request, or cost report; each instance of inappropriate prescribing of drugs for a Medicaid recipient as determined by competent peer

judgment; and each false or erroneous Medicaid claim leading to an overpayment to a provider is considered, for the purposes of this section, to be a separate violation.

- (d) Immediate suspension, if the agency has received information of patient abuse or neglect or of any act prohibited by s. 409.920. Upon suspension, the agency must issue an immediate final order under s. 120.569(2)(n).
- (e) A fine, not to exceed \$10,000, for a violation of paragraph (15)(i).
- (f) Imposition of liens against provider assets, including, but not limited to, financial assets and real property, not to exceed the amount of fines or recoveries sought, upon entry of an order determining that such moneys are due or recoverable.
- (g) Prepayment reviews of claims for a specified period of time.
- (h) Comprehensive followup reviews of providers every 6 months to ensure that they are billing Medicaid correctly.
- (i) Corrective-action plans that $\frac{\text{would}}{\text{providers}}$ for up to 3 years and that $\frac{\text{are}}{\text{monitored}}$ by the agency every 6 months while in effect.
- (j) Other remedies as permitted by law to effect the recovery of a fine or overpayment.

If a provider voluntarily relinquishes its Medicaid provider number after receiving written notice that the agency is conducting, or has conducted, an audit or investigation and the sanction of suspension or termination will be imposed for noncompliance discovered as a result of the audit or investigation, the agency shall impose the sanction of

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

- (21) When making a determination that an overpayment has occurred, the agency shall prepare and issue an audit report to the provider showing the calculation of overpayments. The agency's determination shall be based solely upon information available to it before issuance of the audit report and, in the case of documentation obtained to substantiate claims for Medicaid reimbursement, based solely upon contemporaneous records.
- (22) The audit report, supported by agency work papers, showing an overpayment to a provider constitutes evidence of the overpayment. A provider may not present or elicit testimony, either on direct examination or cross-examination in any court or administrative proceeding, regarding the purchase or acquisition by any means of drugs, goods, or supplies; sales or divestment by any means of drugs, goods, or supplies; or inventory of drugs, goods, or supplies, unless such acquisition, sales, divestment, or inventory is documented by written invoices, written inventory records, or other competent written documentary evidence maintained in the normal course of the provider's business. Testimony or evidence that is not based upon contemporaneous records or that was not furnished to the agency within 21 days after the issuance of the audit report is inadmissible in an administrative hearing on a Medicaid overpayment or an administrative sanction. Notwithstanding the

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applicable rules of discovery, all documentation <u>to</u> that will be offered as evidence at an administrative hearing on a Medicaid overpayment <u>or an administrative sanction</u> must be exchanged by all parties at least 14 days before the administrative hearing or <u>must be</u> excluded from consideration.

- (25) (a) The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid recipients. If it is determined that fraud, willful misrepresentation, abuse, or a crime did not occur, the payments withheld must be paid to the provider within 14 days after such determination with interest at the rate of 10 percent a year.

 Any money withheld in accordance with this paragraph shall be placed in a suspended account, readily accessible to the agency, so that any payment ultimately due the provider shall be made within 14 days.
- (b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.
- (c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of determination of the overpayment by the agency, and payment arrangements regarding overpayments and fines must be made within 30 days after the date of the final order and are not subject to further

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appeal at the conclusion of legal proceedings. A provider who does not enter into or adhere to an agreed-upon repayment schedule may be terminated by the agency for nonpayment or partial payment.

- (d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a stipulation or settlement, may collect the moneys owed by all means allowable by law, including, but not limited to, notifying any fiscal intermediary of Medicare benefits that the state has a superior right of payment. Upon receipt of such written notification, the Medicare fiscal intermediary shall remit to the state the sum claimed.
- (e) The agency may institute amnesty programs to allow Medicaid providers the opportunity to voluntarily repay overpayments. The agency may adopt rules to administer such programs.
- (28) Venue for all Medicaid program integrity $\frac{\text{overpayment}}{\text{overpayment}}$ cases $\frac{\text{lies}}{\text{shall lie}}$ 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 <u>person's or provider's Medicaid-related and non-Medicaid-related records in order to determine the total output of a provider's practice to reconcile quantities of goods or services billed to Medicaid with quantities of goods or services used in the provider's total practice.</u>
- (30) The agency shall terminate a provider's participation in the Medicaid program if the provider fails to reimburse an overpayment or pay a fine that has been determined by final

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order, not subject to further appeal, within 30 35 days after the date of the final order, unless the provider and the agency have entered into a repayment agreement.

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

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

409.920 Medicaid provider fraud.-

(8) A person who provides the state, any state agency, any of the state's political subdivisions, or any agency of the state's political subdivisions with information about fraud or suspected fraudulent acts fraud by a Medicaid provider, including a managed care organization, is immune from civil liability for libel, slander, or any other relevant tort for providing any the information about fraud or suspected fraudulent acts, unless the person acted with knowledge that the information was false or with reckless disregard for the truth or falsity of the information. For purposes of this subsection, the term "fraudulent acts" includes actual or suspected fraud,

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

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

- 409.967 Managed care plan accountability.-
- (2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:
 - (c) Access.-
- 1. Providers.—The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies is may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. A plan may contract with a new hospital facility before

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

- 2. Prescribed drugs.-
- <u>a. If establishing a prescribed drug formulary or preferred</u> drug list, a managed care plan must:
- (I) Provide a broad range of therapeutic options for the treatment of disease states consistent with the general needs of an outpatient population. Whenever feasible, the formulary or preferred drug list should include at least two products in a therapeutic class;
- (II) Include coverage via prior authorization for each drug newly approved by the federal Food and Drug Administration until the plan's Pharmaceutical and Therapeutics Committee reviews such drug for inclusion on the formulary. The timing of the formulary review must comply with s. 409.91195; and
 - (III) Provide a response within 24 hours after receipt of

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all necessary information from the medical provider for a request for prior authorization and provide a procedure for escalating a delayed prior authorization request to the pharmacy management team for resolution or to override other medical management tools.

- <u>b.</u> Each managed care plan <u>shall</u> <u>must</u> publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. <u>Each plan must ensure that the prior</u> <u>authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers.</u>
- c. The managed care plan must continue to permit an enrollee who was receiving a prescription drug that was on the plan's formulary and subsequently removed or changed to continue to receive that drug if the provider submits a written request that demonstrates that the drug is medically necessary, and the enrollee meets clinical criteria to receive the drug.
- <u>d. A managed care plan that imposes a step-therapy or a fail-first protocol must do so in accordance with the following:</u>
- (I) If prescribed drugs for the treatment of a medical condition are restricted for use by the plan through a steptherapy or fail-first protocol, the plan must provide the prescriber with access to a clear and convenient process to expeditiously request a prior authorization that includes a procedure for escalation to the pharmacy management team if not resolved in a timely manner.

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

- (A) Has been ineffective in the treatment of the enrollee's disease or medical condition;
- (B) Is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the enrollee and known characteristics of the drug regimen; or
- (C) Will cause or will likely cause an adverse reaction or other physical harm to the enrollee.
- (III) The pharmacy management team shall work directly with the medical provider to bring the prior-authorization request to a clinically appropriate, cost-effective, and timely resolution.
- <u>e.</u> For <u>enrollees</u> <u>Medicaid recipients</u> diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.
 - 3. Prior authorization.—
- a. Each managed care plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers.
- b. If a drug, determined to be medically necessary and prescribed for an enrollee by a physician using sound clinical

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judgment, is subject to prior authorization and approved, the managed care plan must provide for sufficient refills to complete the duration of the prescription. If the medication is still clinically appropriate for ongoing therapy after the initial prior authorization expires, the plan must provide a process of expedited review to evaluate ongoing therapy.

- c. If a prescribed drug requires prior authorization, the managed care plan shall reimburse the pharmacist for dispensing a 72-hour supply of oral maintenance medications to the enrollee and process the prior authorization request. Dispensing a 72-hour supply must be consistent with laws that govern pharmacy practice and controlled substances. The managed care plan shall process all prior authorization requests in as timely a manner as possible.
- $\underline{\text{d.3.}}$ Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for prescribed drugs $\underline{\text{any service}}$ electronically.
- Section 9. Subsection (11) is added to section 429.23, Florida Statutes, to read:
- 429.23 Internal risk management and quality assurance program; adverse incidents and reporting requirements.—
- (11) The agency shall annually submit a report to the Legislature on adverse incident reports by assisted living facilities. The report must include the following information arranged by county:
 - (a) A total number of adverse incidents;
- (b) A listing, by category, of the type of adverse incidents occurring within each category and the type of staff involved;

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

- (d) Types of liability claims filed based on an adverse incident report or reportable injury; and
- (e) Disciplinary action taken against staff, categorized by the type of staff involved.

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

429.26 Appropriateness of placements; examinations of residents.—

- (9) If, at any time after admission to a facility, agency personnel question whether a resident needs care beyond that which the facility is licensed to provide, the agency may require the resident to be physically examined by a licensed physician, licensed physician assistant, or certified nurse practitioner. To the extent possible, the examination must be performed by the resident's preferred physician, physician assistant, or nurse practitioner and paid for by the resident with personal funds, except as provided in s. 429.18(2). This subsection does not preclude the agency from imposing sanctions for violations of subsection (1).
- (a) Following examination, the examining physician, physician assistant, or nurse practitioner shall complete and sign a medical form provided by the agency. The completed medical form must be submitted to the agency within 30 days after the date the facility owner or administrator was notified by the agency that a physical examination is required.

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

- (c) A resident who is determined by the medical review team to be inappropriately residing in a facility shall be given 30 days' written notice to relocate by the owner or administrator, unless the resident's continued residence in the facility presents an imminent danger to the health, safety, or welfare of the resident or a substantial probability exists that death or serious physical harm to the resident would result if the resident is allowed to remain in the facility.
- (10) If a mental health resident appears to have needs in addition to those identified in the community living support plan, the agency may require an evaluation by a mental health professional, as determined by the Department of Children and Family Services.
- (11) A facility may not be required to retain a resident who requires more services or care than the facility is able to provide in accordance with its policies and criteria for admission and continued residency.

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

456.0635 <u>Health care</u> <u>Medicaid</u> fraud; disqualification for license, certificate, or registration.—

- (1) <u>Health care</u> <u>Medicaid</u> fraud in the practice of a health care profession is prohibited.
- (2) Each board <u>under</u> within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to <u>an</u> any examination and refuse to issue or renew a license, certificate, or registration to <u>an</u> any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant, has been:
- (a) <u>Has been</u> convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, <u>or</u> chapter 893, <u>or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration <u>21 U.S.C. ss. 801-970</u>, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or <u>plea pleas</u> ended: more than 15 years prior to the date of the application;</u>
- 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

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before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

- 3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.
- (b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.
- $\underline{\text{(c)}}$ Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the <u>candidate or</u> applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.÷
- (d) (e) Has been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the candidate or applicant has been in good standing with that a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years before prior to the date of the application.
- (e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which

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was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

- (3) The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:
- (a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the applicant is currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of that program. Any such conviction or plea excludes the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:
- 1. For felonies of the first or second degree, more than 15 years before the date of application.
- 2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).
- 3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.
- (b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation

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for such conviction or plea ended more than 15 years before the date of the application.

- (c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.
- (d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state

 Medicaid program, unless the applicant has been in good standing with that state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.
- (e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.
- $\underline{(4)}$ Licensed health care practitioners shall report allegations of <u>health care</u> <u>Medicaid</u> fraud to the department, regardless of the practice setting in which the alleged <u>health</u> care <u>Medicaid</u> fraud occurred.
- (5)(4) The acceptance by a licensing authority of a licensee's candidate's relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care Medicaid fraud or similar charges constitutes the permanent revocation of the license.
- Section 12. Effective July 1, 2012, present subsections (14) and (15) of section 456.036, Florida Statutes, are renumbered as subsections (15) and (16), respectively, and a new subsection (14) is added to that section, to read:

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456.036 Licenses; active and inactive status; delinquency.-

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

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

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

- (1) The department shall issue an emergency order suspending the license of any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication, to:
- (a) A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or under 42 U.S.C. ss. 1395-1396; or
- (b) A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program.

Section 14. Subsection (3) of section 458.309, Florida

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1306 Statutes, is amended to read:

458.309 Rulemaking authority.-

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

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

459.005 Rulemaking authority.-

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

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shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.

Section 16. Subsections (3), (4), and (5) of section 463.002, Florida Statutes, are amended to read:

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

- (3) (a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.
- (b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe topical ocular pharmaceutical agents."
- (c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.
- (4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe topical ocular pharmaceutical agents.
- (5) "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of topical ocular pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including topical ocular pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal

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1364 conditions of the human eyes and their appendages.

Section 17. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.-

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

Section 18. Section 463.0055, Florida Statutes, is amended to read:

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

- (1) (a) Certified optometrists may administer and prescribe topical ocular pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise prohibited from administering or prescribing topical ocular pharmaceutical agents.
- (b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must complete a course and subsequent examination on general and ocular pharmacology which have a particular emphasis on the ingestion of oral pharmaceutical agents and the side effects of those agents. For certified optometrists licensed

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

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

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

- (b) The <u>topical</u> formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ocular pharmaceutical agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.
- (c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:
- 1. Does not protect the public from any significant and discernible harm or damages;
- 2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or
- 3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.
- However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.
- (d) Upon adoption of the <u>topical</u> formulary required by this section, and upon each addition, deletion, or modification to the <u>topical</u> formulary, the board shall mail a copy of the

588-03223-12 20121316c1 1451 amended topical formulary to each certified optometrist and to 1452 each pharmacy licensed by the state. 1453 (3) In addition to the formulary of topical ocular pharmaceutical agents in subsection (2), there is created a 1454 1455 statutory formulary of oral pharmaceutical agents, which include 1456 the following agents: 1457 (a) The following analgesics, or their generic or therapeutic equivalents, which may not be administered or 1458 1459 prescribed for more than 72 hours without consultation with a 1460 physician licensed under chapter 458 or chapter 459 who is 1461 skilled in diseases of the eye: 1462 1. Tramadol hydrochloride. 1463 2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg. 1464 (b) The following antibiotics, or their generic or 1465 therapeutic equivalents: 1466 1. Amoxicillin. 1467 2. Azithromycin. 1468 3. Ciprofloxacin. 1469 4. Dicloxacillin. 1470 5. Doxycycline. 1471 6. Keflex. 1472 7. Minocycline. 1473 (c) The following antivirals, or their generic or 1474 therapeutic equivalents: 1475 1. Acyclovir. 1476 2. Famciclovir. 1477 3. Valacyclovir. 1478 (d) The following oral anti-glaucoma agents, or their

generic or therapeutic equivalents, which may not be

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1480 administered or prescribed for more than 72 hours without

1481 consultation with a physician licensed under chapter 458 or

1482 chapter 459 who is skilled in diseases of the eye:

1. Acetazolamide.

2. Methazolamide.

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

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

Section 19. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.-

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

Section 20. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

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463.006 Licensure and certification by examination.-

- (2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the <u>use topical</u> application and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.
- (3) Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe topical ocular pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 21. Subsections (1) and (2) of section 463.0135, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

463.0135 Standards of practice. -

- (1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required.
- (2) A licensed practitioner diagnosing angle closure, neovascular, infantile, or congenital forms of glaucoma shall promptly and without unreasonable delay refer the patient to a

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

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

Section 22. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.-

- (3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any systemic drugs for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.
- (4) Surgery of any kind, including the use of lasers, is expressly prohibited. For purposes of this subsection, the term "surgery" means a procedure using an instrument, including lasers, scalpels, or needles, in which human tissue is cut, burned, or vaporized by incision, injection, ultrasound, laser, or radiation. The term includes procedures using instruments that require closing by suturing, clamping, or another such

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

Section 23. Section 463.0141, Florida Statutes, is created to read:

- 463.0141 Reports of adverse incidents in the practice of optometry.—
- (1) Any adverse incident that occurs on or after January 1, 2013, in the practice of optometry must be reported to the department in the accordance with this section.
- (2) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.
- (3) For purposes of notification to the department, the term "adverse incident," as used in this section, means an event that is associated in whole or in part with the prescribing of an oral ocular pharmaceutical agent and that results in one of the following:
- (a) Any condition that requires the transfer of a patient to a hospital licensed under chapter 395;
- (b) Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459, other than a referral or a consultation required under this chapter;
 - (c) Permanent physical injury to the patient;
- 1594 (d) Partial or complete permanent loss of sight by the patient; or

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

Section 24. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

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

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

Section 25. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

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

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

Section 26. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

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

Section 27. Paragraph (a) of subsection (54) of section 499.003, Florida Statutes, is amended to read:

- 499.003 Definitions of terms used in this part.—As used in this part, the term:
- (54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
- (a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in

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

- 1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.
- 2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
- 3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.
- 4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:
- a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a

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

- b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.
- c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.
- d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.
- d.e. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.
- e.f. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the

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1712 contractor or subcontractor required under sub-subparagraph e.

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

Section 28. Subsection (4) of section 766.102, Florida Statutes, is amended to read:

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

- (4) (a) The Legislature is cognizant of the changing trends and techniques for the delivery of health care in this state and the discretion that is inherent in the diagnosis, care, and treatment of patients by different health care providers. The failure of a health care provider to order, perform, or administer supplemental diagnostic tests <u>is shall</u> not be actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care.
- (b) The claimant has the burden of proving by clear and convincing evidence that the alleged actions of the health care provider represent a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests.

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Section 29. Paragraph (b) of subsection (6) of section 766.106, Florida Statutes, is amended to read:

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

- (6) INFORMAL DISCOVERY.-
- (b) Informal discovery may be used by a party to obtain unsworn statements, the production of documents or things, and physical and mental examinations, and ex parte interviews, as follows:
- 1. Unsworn statements.—Any party may require other parties to appear for the taking of an unsworn statement. Such statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party. A party desiring to take the unsworn statement of any party must give reasonable notice in writing to all parties. The notice must state the time and place for taking the statement and the name and address of the party to be examined. Unless otherwise impractical, the examination of any party must be done at the same time by all other parties. Any party may be represented by counsel at the taking of an unsworn statement. An unsworn statement may be recorded electronically, stenographically, or on videotape. The taking of unsworn statements is subject to the provisions of the Florida Rules of Civil Procedure and may be terminated for abuses.
- 2. Documents or things.—Any party may request discovery of documents or things. The documents or things must be produced, at the expense of the requesting party, within 20 days after the date of receipt of the request. A party is required to produce

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discoverable documents or things within that party's possession or control. Medical records shall be produced as provided in s. 1772 766.204.

- 3. Physical and mental examinations.—A prospective defendant may require an injured claimant to appear for examination by an appropriate health care provider. The prospective defendant shall give reasonable notice in writing to all parties as to the time and place for examination. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The practicality of a single examination must be determined by the nature of the claimant's condition, as it relates to the liability of each prospective defendant. Such examination report is available to the parties and their attorneys upon payment of the reasonable cost of reproduction and may be used only for the purpose of presuit screening. Otherwise, such examination report is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- 4. Written questions.—Any party may request answers to written questions, the number of which may not exceed 30, including subparts. A response must be made within 20 days after receipt of the questions.
- 5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn

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

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

Section 30. Section 766.1091, Florida Statutes, is created to read:

766.1091 Voluntary binding arbitration; damages.-

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

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

Section 31. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

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

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

Section 32. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

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

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

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1857 463 may not administer or prescribe pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug 1859 Abuse Prevention and Control Act.

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

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

Section 34. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.