Amendment No. ____ (for drafter's use only)

	CHAMBER ACTION
	Senate House ·
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5	ORIGINAL STAMP BELOW
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11	Representative(s) Farkas offered the following:
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13	Amendment (with title amendment)
14	On page 43 from line 14 through page 46, line 2,
15	remove: all of said lines
16	
17	and insert:
18	Section 14. Section 456.053, Florida Statutes, is
19	amended to read:
20	456.053 Financial arrangements between referring
21	health care providers and providers of health care services
22	(1) SHORT TITLEThis section may be cited as the
23	"Patient Self-Referral Act of 1992."
24	(2) LEGISLATIVE INTENTIt is recognized by the
25	Legislature that the referral of a patient by a health care
26	provider to a provider of health care services in which the
27	referring health care provider has an investment interest
28	represents a potential conflict of interest. The Legislature
29	finds these referral practices may limit or eliminate
30	competitive alternatives in the health care services market,
31	may result in overutilization of health care services, may

increase costs to the health care system, and may adversely 1 2 affect the quality of health care. The Legislature also 3 recognizes, however, that it may be appropriate for providers to own entities providing health care services, and to refer 4 5 patients to such entities, as long as certain safeguards are present in the arrangement. In respect to the kidney dialysis 6 7 industry, the Florida Legislature recognizes that publicly 8 held corporations, as defined in this section, provide the majority of dialysis and clinical laboratory services to 9 10 dialysis patients and that all provisions within subsection 11 6) of this act shall be applicable to all physicians 12 providing dialysis services with an investment interest or is 13 an investor. It is the intent of the Legislature to provide guidance to health care providers regarding prohibited patient 14 15 referrals between health care providers and entities providing health care services and to protect the people of Florida from 16 17 unnecessary and costly health care expenditures. Furthermore, it is the intent of the Legislature to prohibit physicians 18 from making a referral for designated health services to an 19 entity with which the physician or a member of the physician's 20 immediate family has an investment interest or is an investor. 21 22

- (3) DEFINITIONS.--For the purpose of this section, the word, phrase, or term:
- (a) "Board" means any of the following boards relating to the respective professions: the Board of Medicine as created in s. 458.307; the Board of Osteopathic Medicine as created in s. 459.004; the Board of Chiropractic Medicine as created in s. 460.404; the Board of Podiatric Medicine as created in s. 461.004; the Board of Optometry as created in s. 463.003; the Board of Pharmacy as created in s. 465.004; and the Board of Dentistry as created in s. 466.004.

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- (b) "Comprehensive rehabilitation services" means services that are provided by health care professionals licensed under part I or part III of chapter 468 or chapter 486 to provide speech, occupational, or physical therapy services on an outpatient or ambulatory basis.
- (c) "Designated health services" means, for purposes of this section, clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services.
- (d) "Diagnostic imaging services" means magnetic resonance imaging, nuclear medicine, angiography, arteriography, computed tomography, positron emission tomography, digital vascular imaging, bronchography, lymphangiography, splenography, ultrasound, EEG, EKG, nerve conduction studies, and evoked potentials.
- (e) "Direct supervision" means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.
- (f) "Entity" means any individual, partnership, firm, corporation, or other business entity.
- (g) "Fair market value" means value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes, not taking into account its intended use, and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.
 - (h) "Group practice" means a group of two or more

health care providers legally organized as a partnership, professional corporation, or similar association:

- 1. In which each health care provider who is a member of the group provides substantially the full range of services which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;
- 2. For which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and
- 3. In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.
- (i) "Health care provider" means any physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461, or any health care provider licensed under chapter 463 or chapter 466.
- (j) "Immediate family member" means a health care
 provider's spouse, child, child's spouse, grandchild,
 grandchild's spouse, parent, parent-in-law, or sibling.
- (k) "Investment interest" means an equity or debt security issued by an entity, including, without limitation, shares of stock in a corporation, units or other interests in a partnership, bonds, debentures, notes, or other equity interests or debt instruments. The following investment interests shall be excepted from this definition:
- 1. An investment interest in an entity that is the sole provider of designated health services in a rural area;

- 2. An investment interest in notes, bonds, debentures, or other debt instruments issued by an entity which provides designated health services, as an integral part of a plan by such entity to acquire such investor's equity investment interest in the entity, provided that the interest rate is consistent with fair market value, and that the maturity date of the notes, bonds, debentures, or other debt instruments issued by the entity to the investor is not later than October 1, 1996.
- 3. An investment interest in real property resulting in a landlord-tenant relationship between the health care provider and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant or exceeds fair market value; or
- 4. An investment interest in an entity which owns or leases and operates a hospital licensed under chapter 395 or a nursing home facility licensed under chapter 400.
- (1) "Investor" means a person or entity owning a legal or beneficial ownership or investment interest, directly or indirectly, including, without limitation, through an immediate family member, trust, or another entity related to the investor within the meaning of 42 C.F.R. s. 413.17, in an entity.
- (m) "Outside referral for diagnostic imaging services" means a referral of a patient to a group practice or sole provider for diagnostic imaging services by a physician who is not a member of the group practice or of the sole provider's practice and who does not have an investment interest in the group practice or sole provider's practice, for which the group practice or sole provider billed for both the technical

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and the professional fee for the patient, and the patient did not become a patient of the group practice or sole provider's practice.

- (n) "Patient of a group practice" or "patient of a sole provider" means a patient who receives a physical examination, evaluation, diagnosis, and development of a treatment plan if medically necessary by a physician who is a member of the group practice or the sole provider's practice.
- (o) "Referral" means any referral of a patient by a health care provider for health care services, including, without limitation:
- 1. The forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies designated health services or any other health care item or service; or
- 2. The request or establishment of a plan of care by a health care provider, which includes the provision of designated health services or other health care item or service.
- 3. The following orders, recommendations, or plans of care shall not constitute a referral by a health care provider:
 - a. By a radiologist for diagnostic-imaging services.
- b. By a physician specializing in the provision of radiation therapy services for such services.
- c. By a medical oncologist for drugs and solutions to be prepared and administered intravenously to such oncologist's patient, as well as for the supplies and equipment used in connection therewith to treat such patient for cancer and the complications thereof.
 - d. By a cardiologist for cardiac catheterization

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- e. By a pathologist for diagnostic clinical laboratory tests and pathological examination services, if furnished by or under the supervision of such pathologist pursuant to a consultation requested by another physician.
- By a health care provider who is the sole provider or member of a group practice for designated health services or other health care items or services that are prescribed or provided solely for such referring health care provider's or group practice's own patients, and that are provided or performed by or under the direct supervision of such referring health care provider or group practice; provided, however, that effective July 1, 1999, a physician licensed pursuant to chapter 458, chapter 459, chapter 460, or chapter 461 may refer a patient to a sole provider or group practice for diagnostic imaging services, excluding radiation therapy services, for which the sole provider or group practice billed both the technical and the professional fee for or on behalf of the patient, if the referring physician has no investment interest in the practice. The diagnostic imaging service referred to a group practice or sole provider must be a diagnostic imaging service normally provided within the scope of practice to the patients of the group practice or sole provider. The group practice or sole provider may accept no more that 15 percent of their patients receiving diagnostic imaging services from outside referrals, excluding radiation therapy services.
- g. By a health care provider for services provided by an ambulatory surgical center licensed under chapter 395.
- h. By a health care provider for diagnostic clinical laboratory services where such services are directly related

to renal dialysis.

 $\underline{\text{h.i.}}$ By a urologist for lithotripsy services.

 $\underline{\text{i.j.}}$ By a dentist for dental services performed by an employee of or health care provider who is an independent contractor with the dentist or group practice of which the dentist is a member.

 $\underline{j.k.}$ By a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice.

 \underline{k} : By a nephrologist for renal dialysis services and supplies, except clinical laboratory services.

- l. By a home care physician whose principal medical practice consists of treating patients in the patient's private homes. The "present in the office suite" requirements of this section are met if the referring physician or qualified person, technician, or nurse provides the prescribed designated health service to the patient in the patient's private home. For purposes of this section, a private home does not include a nursing, long-term care, or other facility or institution.
- (p) "Present in the office suite" means that the physician is actually physically present; provided, however, that the health care provider is considered physically present during brief unexpected absences as well as during routine absences of a short duration if the absences occur during time periods in which the health care provider is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirement in the Medicare program for a particular level of health care provider supervision.
 - (q) "Rural area" means a county with a population

density of no greater than 100 persons per square mile, as defined by the United States Census.

- (r) "Sole provider" means one health care provider licensed under chapter 458, chapter 459, chapter 460, or chapter 461, who maintains a separate medical office and a medical practice separate from any other health care provider and who bills for his or her services separately from the services provided by any other health care provider. A sole provider shall not share overhead expenses or professional income with any other person or group practice.
- (4) REQUIREMENTS FOR SELF-REFERRALS AS DEFINED IN
 FEDERAL LAW.--Notwithstanding the provisions of this act, the
 prohibitions for self-referrals shall only be governed
 consistent with the provisions pursuant to 42 U.S.C., ss.
 1395nn, "The Stark Law", and accompanying federal regulations,
 as interpreted and applied, at 42 C.F.F. ss. 411.1, et seq.,
 for all licensed providers as set forth in this section.
- $\underline{\text{(5)}}$ (4) REQUIREMENTS FOR ACCEPTING OUTSIDE REFERRALS FOR DIAGNOSTIC IMAGING.--
- (a) A group practice or sole provider accepting outside referrals for diagnostic imaging services is required to comply with the following conditions:
- 1. Diagnostic imaging services must be provided exclusively by a group practice physician or by a full-time or part-time employee of the group practice or of the sole provider's practice.
- 2. All equity in the group practice or sole provider's practice accepting outside referrals for diagnostic imaging must be held by the physicians comprising the group practice or the sole provider's practice, each of whom must provide at least 75 percent of his or her professional services to the

group. Alternatively, the group must be incorporated under chapter 617 and must be exempt under the provisions of s. 501(c)(3) of the Internal Revenue Code and be part of a foundation in existence prior to January 1, 1999, that is created for the purpose of patient care, medical education, and research.

- 3. A group practice or sole provider may not enter into, extend or renew any contract with a practice management company that provides any financial incentives, directly or indirectly, based on an increase in outside referrals for diagnostic imaging services from any group or sole provider managed by the same practice management company.
- 4. The group practice or sole provider accepting outside referrals for diagnostic imaging services must bill for both the professional and technical component of the service on behalf of the patient, and no portion of the payment, or any type of consideration, either directly or indirectly, may be shared with the referring physician.
- 5. Group practices or sole providers that have a Medicaid provider agreement with the Agency for Health Care Administration must furnish diagnostic imaging services to their Medicaid patients and may not refer a Medicaid recipient to a hospital for outpatient diagnostic imaging services unless the physician furnishes the hospital with documentation demonstrating the medical necessity for such a referral. If necessary, the Agency for Health Care Administration may apply for a federal waiver to implement this subparagraph.
- 6. All group practices and sole providers accepting outside referrals for diagnostic imaging shall report annually to the Agency for Health Care Administration providing the number of outside referrals accepted for diagnostic imaging

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services and the total number of all patients receiving diagnostic imaging services.

- (b) If a group practice or sole provider accepts an outside referral for diagnostic imaging services in violation of this subsection or if a group practice or sole provider accepts outside referrals for diagnostic imaging services in excess of the percentage limitation established in subparagraph (a)2., the group practice or the sole provider shall be subject to the penalties in subsection(6) $\frac{(5)}{(5)}$.
- (c) Each managing physician member of a group practice and each sole provider who accepts outside referrals for diagnostic imaging services shall submit an annual attestation signed under oath to the Agency for Health Care Administration which shall include the annual report required under subparagraph (a)6. and which shall further confirm that each group practice or sole provider is in compliance with the percentage limitations for accepting outside referrals and the requirements for accepting outside referrals listed in paragraph (a). The agency may verify the report submitted by group practices and sole providers.
- $\underline{(6)}\overline{(5)}$ PROHIBITED REFERRALS AND CLAIMS FOR PAYMENT.--Except as provided in this section:
- (a) A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest.
- (b) A health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor unless:
 - 1. The provider's investment interest is in registered

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securities purchased on a national exchange or over-the-counter market and issued by a publicly held corporation:

- a. Whose shares are traded on a national exchange or on the over-the-counter market; and
- b. Whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million; or
- 2. With respect to an entity other than a publicly held corporation described in subparagraph 1., and a referring provider's investment interest in such entity, each of the following requirements are met:
- a. No more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals to the entity.
- b. The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are no different from the terms offered to investors who are not in a position to make such referrals.
- c. The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are not related to the previous or expected volume of referrals from that investor to the entity.
- d. There is no requirement that an investor make referrals or be in a position to make referrals to the entity as a condition for becoming or remaining an investor.
- 3. With respect to either such entity or publicly held corporation:
- a. The entity or corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

- b. The amount distributed to an investor representing a return on the investment interest is directly proportional to the amount of the capital investment, including the fair market value of any preoperational services rendered, invested in the entity or corporation by that investor.
- 4. Each board and, in the case of hospitals, the Agency for Health Care Administration, shall encourage the use by licensees of the declaratory statement procedure to determine the applicability of this section or any rule adopted pursuant to this section as it applies solely to the licensee. Boards shall submit to the Agency for Health Care Administration the name of any entity in which a provider investment interest has been approved pursuant to this section, and the Agency for Health Care Administration shall adopt rules providing for periodic quality assurance and utilization review of such entities.
- (c) No claim for payment may be presented by an entity to any individual, third-party payor, or other entity for a service furnished pursuant to a referral prohibited under this section.
- (d) If an entity collects any amount that was billed in violation of this section, the entity shall refund such amount on a timely basis to the payor or individual, whichever is applicable.
- (e) Any person that presents or causes to be presented a bill or a claim for service that such person knows or should know is for a service for which payment may not be made under paragraph (c), or for which a refund has not been made under paragraph (d), shall be subject to a civil penalty of not more than \$15,000 for each such service to be imposed and collected by the appropriate board.

- (f) Any health care provider or other entity that enters into an arrangement or scheme, such as a cross-referral arrangement, which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil penalty of not more than \$100,000 for each such circumvention arrangement or scheme to be imposed and collected by the appropriate board.
- (g) A violation of this section by a health care provider shall constitute grounds for disciplinary action to be taken by the applicable board pursuant to s. 458.331(2), s. 459.015(2), s. 460.413(2), s. 461.013(2), s. 463.016(2), or s. 466.028(2). Any hospital licensed under chapter 395 found in violation of this section shall be subject to the rules adopted by the Agency for Health Care Administration pursuant to s. 395.0185(2).
- (h) Any hospital licensed under chapter 395 that discriminates against or otherwise penalizes a health care provider for compliance with this act.
- (i) The provision of paragraph (a) shall not apply to referrals to the offices of radiation therapy centers managed by an entity or subsidiary or general partner thereof, which performed radiation therapy services at those same offices prior to April 1, 1991, and shall not apply also to referrals for radiation therapy to be performed at no more than one additional office of any entity qualifying for the foregoing exception which, prior to February 1, 1992, had a binding purchase contract on and a nonrefundable deposit paid for a linear accelerator to be used at the additional office. The physical site of the radiation treatment centers affected by

this provision may be relocated as a result of the following factors: acts of God; fire; strike; accident; war; eminent 2 3 domain actions by any governmental body; or refusal by the 4 lessor to renew a lease. A relocation for the foregoing 5 reasons is limited to relocation of an existing facility to a 6 replacement location within the county of the existing 7 facility upon written notification to the Office of Licensure and Certification. 8 (j) A health care provider who meets the requirements 9 10 of paragraphs (b) and (i) must disclose his or her investment interest to his or her patients as provided in s. 456.052. 11 12 13 ======= T I T L E 14 A M E N D M E N T ======== 15 And the title is amended as follows: On page 5, line 8, after the semicolon, 16 17 insert: 18 19 providing legislative intent; providing the applicability of the Federal "Stark Law" for 20 licensed health providers in Florida; 21 22 23 24 25 26 27 28 29 30 31