Final Order No. DOH-04-0921-DS-MQA
FILED DATE - 8-17-04
Department of Health
By: Heather Coleman
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY STATEMENT

TALLAHASSEE NEUROLOGICAL CLINIC, P.A.
_____/

FINAL ORDER

This matter came before the Board of Medicine (hereinafter the "Board") on June 5, 2004, in Tampa, Florida, for consideration of the referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on April 9, 2004, in the Vol. 30, No. 15, in the Florida Administrative Weekly.

The petition filed by TALLAHASSEE NEUROLOGICAL CLINIC, P.A. inquired as to whether under Section 456.053, Florida Statutes, (Patient Self-Referral Act of 1992), may a single group practice wholly own a separate legal entity which provides diagnostic imaging services to the group practice and other patients and still qualify for the exception to the definition of "referral" set forth in Section 456.053(3)(o), Florida Statutes?

FINDINGS OF FACTS

1. The Petitioner, TALLAHASSEE NEUROLOGICAL CLINIC, P.A., (hereinafter the "Clinic" or the "Petitioner") is a single legal entity located in Tallahassee, Florida that qualifies as a "group practice" pursuant to Section 456.053(3)(h), Florida Statutes.

2. The Clinic wishes to form a separate entity (hereinafter the "Subsidiary") which will own or lease magnetic resonance imaging (MRI) equipment and provide MRIs to the Clinic's patients and patients from other practices.

3. The Subsidiary will be a limited liability company (LLC) owned in its entirety by the Clinic.

4. The Clinic will, though its subsidiary, offer MRI services to its own patients and to others from other practices in accordance with the requirements for accepting outside referrals under the Patient Self Referral Act of 1992 and the "in-office ancillary services" exception of the United States Stark Act, U.S.C. § 1395nn(b)(2).

CONCLUSIONS OF LAW

5. The Board of Medicine has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

6. The Petition filed in this cause is in substantial compliance with the provisions of 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code.

7. The crux of this inquiry involves the issue of whether the Clinic, a group practice, will lose its "group practice" status if it wholly owns a separate legal entity that provides diagnostic imaging services to the Clinic or other patients. This is significant because if the Clinic does lose its group practice status it will no longer be exempt from the "referral" prohibitions of Section 456.053, Florida Statutes.

8. The Florida Board of Medicine has recognized in a prior declaratory statement that the definition of a "group practice" in Section 456.053(3)(h) of the Florida's Patient Self-Referral Act is, in relevant part, virtually identical to the definition of a "group practice" in the federal Stark Act at 42 U.S.C. § 1395nn (h)(4)(A). In re: Petition for Declaratory Statement of Alan Levin, M.D. and Ameripath, Inc., 19 F.A.L.R. 4525, 4528 (Fla. Bd. of Med. 1997)[1]. However,

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[1]Section 456.053(3)(h), Florida Statutes, reads as follows:

(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,

neither the Board nor the Petitioner have been able to find any statute, rule, court opinions or orders from state agencies that address whether a single group of physicians may own other legal entities for the purpose of providing services to the group practice.

9. This issue, however, has been answered affirmatively with respect to the federal Stark Act. The Stark regulations require that a "group practice" consist of a single legal entity. 42 C.F.R. § 411.352(a). However, both the 1995 Commentary and the 2001 Commentary to this federal regulation authorize a group practice to wholly own a separate entity which provides designated health services to group practice or other patients. In the 1995 Commentary, the U.S. Department of Health and Human Services stated in relevant part:

> As we have said elsewhere in this preamble, we believe that the statute contemplates a group practice that is composed of one single group of physicians who are organized into one legal entity. In short, we do not believe that a group practice can consist of two or more groups of physicians, each organized as separate legal entities.
>
> However, we do not believe the statute precludes a single group practice (that is, one single group of physicians) from owning other legal entities for the purpose of providing services to the group practice. Thus, a group practice could wholly own a separately incorporated laboratory facility which provides laboratory services to group practice or other patients. However, because the group practice physicians have an ownership interest in the laboratory, they could be prohibited from referring to the laboratory, unless an exception applies.

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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.

> The physicians could qualify for the in-office ancillary services exception, provided they meet the requirements for supervision, location, and billing. This exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. In fact, the billing requirement in section 1877(b)(2)(B) allows the services to be billed by the referring physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a "group practice," as defined in section 1877(h)(4), may wholly own separate legal entities for billing or for providing ancillary services.

60 Fed. Reg. 41935-36 (Aug. 14, 1995). In the 2001 Federal Commentary, the Department stated in relevant part:

> As we noted in the August 1995 final regulations, we believe that the statute does not preclude a single group practice from owning other legal entities for the purposes of providing services to the group practice. Thus, to cite the example in the August 1995 final regulation at 60 FR 41936, a group practice could wholly own and separately incorporate a laboratory facility that provides laboratory services to a group practice or other patients. 66 Fed. Reg. 899 (Jan. 4, 2001).

10. In the past the Florida Board of Medicine has looked to the federal standards implementing provisions in the federal Stark Act when interpreting Florida's Patient Self-Referral Act. It followed this approach when it interpreted the requirement in Florida's Patient Self-Referral Act that members of the group render "substantially all" of their services through the group. Levin, supra at 4528. In Levin, the Board ruled:

> Given the magnitude of Medicare and Medicaid services rendered by Florida physicians and the relatively similar language and intent set forth in both the state and federal regulations, it is reasonable for the Board to look to the federal standards implementing the Stark Bill when interpreting the provisions of Florida's Self-Referral Act, where it would not be inconsistent with the plain meaning of and legislative intent of the Florida Act.

Id.

11. Given the above analysis, the Board believes that it should continue to look toward the federal standards implementing provisions of the federal Stark Act when interpreting Florida's Patient Self-Referral Act. Therefore, with respect to the question presented, the Board is of the opinion that Self-Referral Act should, like the Stark Act, be interpreted to permit a "group practice" to wholly own a separate legal entity which provides diagnostic imaging services to the group practice or other patients, without losing the "group practice" exemption to the definition of "referral" under Section 456.053(3)(o), Florida Statutes.

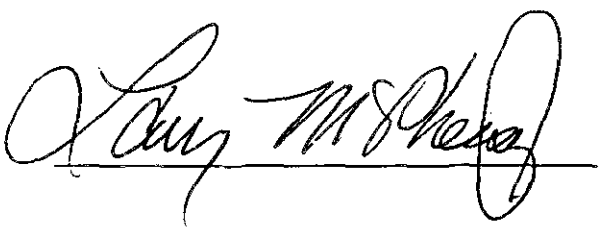
12. The Petitioner's inquiry is answered in the affirmative but the Board is compelled to remind the Petitioner that while it may own a separate legal entity which provides diagnostic imaging services to the group practice and other patients, the Petitioner must operate the group practice in a manner that complies with all the provisions of Section 456.053, Florida Statutes, and in particular, Section 456.053(3)(o)3.f. and (4).

WHEREFORE, the Board hereby finds that the Petitioner, a group practice that wholly owns a separate legal entity which provides diagnostic imaging services to the group practice and other patients, maintains its exception to the definition of "referral" set forth in Section 456.053(3)(o), Florida Statutes.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this 16 day of AUGUST, 2004.

BOARD OF MEDICINE



Larry McPherson, Jr., Executive Director
for Elisabeth Tucker M.D., Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to: Emily S. Waugh, Esquire, Ausley & McMullen, 227 South Calhoun Street, Post Office Box 391 (Zip 32302), Tallahassee, Florida 32301; and by interoffice mail to Edward A. Tellechea, Senior Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050; and Renee Alsobrook, Esquire, Acting General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, on this 17th day of August, 2004.

Shalonda Lee

Deputy Agency Clerk

AUSLEY & MCMULLEN

ATTORNEYS AND COUNSELORS AT LAW

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January 21, 2004

VIA HAND DELIVERY

Mr. Edward A. Tellechea
Assistant Attorney General
Attorney General's Office
400 South Monroe Street
Tallahassee, Florida 32399-6536

RE: Florida Board of Medicine

Dear Mr. Tellechea:

As we recently discussed, our law firm represents Tallahassee Neurological Clinic, P.A. which requests an advisory statement from the Florida Board of Medicine with respect to the following question:

> Under Florida's Patient Self-Referral Act, may a single group practice wholly own a separate legal entity which provides diagnostic imaging services to the group practice and other patients and still qualify for the exception to the definition of "referral" set forth in Section 456.053(3)(o), Florida Statutes?

I. FACTS.

Tallahassee Neurological Clinic, P.A. (the "Clinic") is a single legal entity which is a "group practice" as defined by Section 456.053(3)(h), Florida Statutes. The Clinic wishes to form a separate entity (the "Subsidiary") which will own or lease magnetic resonance imaging ("MRI") equipment and provide MRIs to the Clinic's patients and patients outside the Clinic. The Subsidiary will be a limited liability company whose sole member will be the Clinic. The Clinic will own 100% of the Subsidiary.

The Clinic will, through its Subsidiary, offer MRI services to its own patients and patients outside the Clinic in accordance with Section 456.053(4), Florida Statutes. Provided it is permissible for the MRI equipment to be owned by the Clinic's wholly owned Subsidiary, the Clinic will meet all requirements of: (a) accepting outside referrals under Florida's Patient Self-

Referral Act, and (b) the "in-office ancillary services" exception of the federal Stark Act, 42 U.S.C. § 1395nn(b)(2).

II. LEGAL ANALYSIS.

Section 456.053(3)(o)(3)(f) provides an exclusion from the definition of a "referral" prohibited by Florida's Patient Self-Referral Act of 1992. In general terms, a referral by a member of a "group practice" for health care services prescribed or provided solely for such "group practice's" own patients are not considered referrals. In addition, the "group practice" may accept outside referrals of no more than 15% of its patients receiving diagnostic imaging services.

As the Florida Board of Medicine recognized in another case, the definition of a "group practice" in Section 456.053(3)(h) of the Florida's Patient Self-Referral Act is, in relevant part, virtually identical to the definition of a "group practice" in the federal Stark Act at 42 U.S.C. § 1395nn (h)(4)(A). In re: Petition for Declaratory Statement of Alan Levin, M.D. and Ameripath, Inc., 19 F.A.L.R. 4525, 4528 (Fla. Bd. of Med. 1997). Both the state and federal statutes define a "group practice" in relevant part:

> "Group practice" means a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association.... .

Florida's Patient Self-Referral Act does not specify whether a single group of physicians may own other legal entities for the purpose of providing services to the group practice. To our knowledge, this question has not been addressed by any Florida courts or administrative agencies.

This question has been answered affirmatively with respect to the federal Stark Act. The Stark regulations require that a "group practice" consist of a single legal entity. 42 C.F.R. § 411.352(a). However, both the 1995 Commentary and the 2001 Commentary to this federal regulation authorize a group practice to wholly own a separate entity which provides designated health services to group practice or other patients. In the 1995 Commentary, the U.S. Department of Health and Human Services stated in relevant part:

> As we have said elsewhere in this preamble, we believe that the statute contemplates a group practice that is composed of one single group of physicians who are organized into one legal entity. In short, we do not believe that a group practice can consist of two or more groups of physicians, each organized as separate legal entities.

> However, we do not believe the statute precludes a single group practice (that is, one single group of physicians) from owning other legal entities for the purpose of providing services to the group practice. Thus, a group practice could wholly own a separately incorporated laboratory facility which provides laboratory services to group practice or other patients. However, because the group practice physicians have an ownership interest in the laboratory, they could be prohibited from referring to the laboratory, unless an exception applies.
>
> The physicians could qualify for the in-office ancillary services exception, provided they meet the requirements for supervision, location, and billing. This exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. In fact, the billing requirement in section 1877(b)(2)(B) allows the services to be billed by the referring physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a "group practice," as defined in section 1877(h)(4), may wholly own separate legal entities for billing or for providing ancillary services.

60 Fed. Reg. 41935-36 (Aug. 14, 1995) (emphasis added). In the 2001 federal Commentary, the Department stated in relevant part:

> As we noted in the August 1995 final regulations, we believe that the statute does not preclude a single group practice from owning other legal entities for the purposes of providing services to the group practice. Thus, to cite the example in the August 1995 final regulation at 60 FR 41936, a group practice could wholly own and separately incorporate a laboratory facility that provides laboratory services to a group practice or other patients.

66 Fed. Reg. 899 (Jan. 4, 2001) (emphasis added).

When interpreting Florida's Patient Self-Referral Act, it is appropriate to follow the federal standards implementing similar provisions in the federal Stark Act. The Florida Board of Medicine followed this approach a few years ago when it interpreted the requirement in Florida's Patient Self-Referral Act that members of the group render "substantially all" of their services through the group. Levin, supra at 4528. The Board ruled:

> Given the magnitude of Medicare and Medicaid services rendered by Florida physicians and the relatively similar language and intent set forth in both the state and federal regulations, it is reasonable for the Board to look to the federal standards implementing the Stark Bill when interpreting the provisions of Florida's Self-Referral Act, where it would not be inconsistent with the plain meaning of and legislative intent of the Florida Act.

Id.

With respect to the question presented, we believe Florida's Self-Referral Act should, like the Stark Act, be interpreted to permit a "group practice" to wholly own a separate legal entity which provides diagnostic imaging services to the group practice or other patients, without losing the "group practice" exemption to the definition of "referral" under Florida's Act.

We will be glad to answer any questions or provide additional information which you or the Board might request. We will also be glad to appear before the Board if you believe such might be helpful. Thank you for your assistance.

Sincerely,

Emily S. Waugh

ESW/jg

cc: Tallahassee Neurological Clinic, P.A. (via U.S. Mail)

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456.053 **Financial arrangements between referring health care providers and providers of health care services.--**

(1) SHORT TITLE.--This section may be cited as the "Patient Self-Referral Act of 1992."

(2) LEGISLATIVE INTENT.--It is recognized by the Legislature that the referral of a patient by a health care provider to a provider of health care services in which the referring health care provider has an investment interest represents a potential conflict of interest. The Legislature finds these referral practices may limit or eliminate competitive alternatives in the health care services market, may result in overutilization of health care services, may increase costs to the health care system, and may adversely affect the quality of health care. The Legislature also recognizes, however, that it may be appropriate for providers to own entities providing health care services, and to refer patients to such entities, as long as certain safeguards are present in the arrangement. It is the intent of the Legislature to provide guidance to health care providers regarding prohibited patient referrals between health care providers and entities providing health care services and to protect the people of Florida from unnecessary and costly health care expenditures.

(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.

(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.

(l) "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 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 services.

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.

f. 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 than 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 urologist for lithotripsy services.

i. 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.

j. By a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice.

k. By a nephrologist for renal dialysis services and supplies, except laboratory services.

l. By a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in such private residences, except for services rendered by a home health agency licensed under chapter 400. For purposes of this sub-subparagraph, the term "private residences" includes patient's private homes, independent living centers, and assisted living facilities, but does not include skilled nursing facilities.

(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 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 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 (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.

(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 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 domain actions by any governmental body; or refusal by the lessor to renew a lease. A relocation for the foregoing reasons is limited to relocation of an existing facility to a replacement location within the county of the existing facility upon written notification to the Office of Licensure and Certification.

(j) A health care provider who meets the requirements of paragraphs (b) and (i) must disclose his or her investment interest to his or her patients as provided in s. 456.052.

History.--s. 7, ch. 92-178; s. 89, ch. 94-218; s. 60, ch. 95-144; s. 35, ch. 95-146; s. 8, ch. 96-296; s. 1083, ch. 97-103; s. 78, ch. 97-261; s. 70, ch. 97-264; s. 263, ch. 98-166; s. 62, ch. 98-171; s. 1, ch. 99-356; s. 10, ch. 2000-159; s. 77, ch. 2000-160; s. 14, ch. 2002-389.

Note.--Former s. 455.236; s. 455.654