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9/11/00

Final Order No. DOH-00-2454-DS-MQA
FILED DATE - 12/21/00
Department of Health
By: Vicki R. Kenan
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY STATEMENT
OF DAVID W. SHOEMAKER, M.D.

Petitioner,
_____/

FINAL ORDER

THIS CAUSE came before the Board of Medicine (hereinafter Board) on October 6, 2000, in Orlando, Florida, pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, for the purpose of considering the Petition for Declaratory Statement filed on behalf of David W. Shoemaker, M.D., (hereinafter Petitioner). Petitioner was not present but was represented by Allen R. Grossman, Attorney at Law. Having considered the Petition, the arguments submitted by counsel for the parties, and being otherwise fully advised in the premises, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. Petitioner David W. Shoemaker, M.D., is a board certified ophthalmologist licensed pursuant to Chapter 458, Florida Statutes.

2. Petitioner seeks an interpretation by the Board of Medicine of Section 455.654, Florida Statutes (1999), now at 456.053, Florida Statutes (2000), as applied to his proposed practice activities. Petitioner currently owns refractive laser equipment in his medical practice.

3. In order to defray the high cost of owning and operating such expensive

equipment, Petitioner is contemplating the establishment of a limited liability company (hereinafter Laser L.L.C.) to lease refractive laser equipment and services to an ambulatory surgical center (hereinafter ASC).

4. Petitioner, together with his own family trust will own a 60% interest in Laser L.L.C., and the other 40% interest in Laser L.L.C. will be owned by physician investors, who may at times refer patients to ASC.

5. ASC will be owned by Petitioner and Petitioner's family members and family interests.

6. Laser L.L.C. will obtain an excimer laser and will lease appropriate staff currently employed by Petitioner's medical practice. These transactions will be structured to be consistent with fair market value.

7. Laser L.L.C. will enter into an agreement to provide ASC with equipment, supplies, and staffing necessary for the performance of laser procedures. Laser L.L.C. may also provide ASC with general administrative services such as billing and collection, and public relations/advertising. There will be no obligation or responsibility for Laser L.L.C. to be involved with negotiating, obtaining or maintaining any managed care contracts, practice networks or other patient referral services. Laser L.L.C. intends to bill ASC on a per-case basis for the provided equipment, staff and administrative services. It is anticipated that the pricing will be on a sliding scale with the cost per case decreasing as the volume of laser procedures increases.

8. ASC or Laser L.L.C., on behalf of ASC, will bill globally for all medical services performed at ASC. The professional collections will be provided to the operating physicians. The facility collections will be provided to ASC, offset by the

amount of Laser L.L.C.'s administrative/equipment fee. The actual costs to Laser L.L.C. for services such as advertising on behalf of ASC will be billed as expenses to ASC.

9. This Petition was noticed by the Board in Volume 26, No. 26, page 3119, of the June 26, 2000, Florida Administrative Weekly.

CONCLUSIONS OF LAW

1. The Board has jurisdiction of this matter pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, and Chapters 458 and 456, Florida Statutes.

2. The Petition filed in this cause is in substantial compliance with the provisions of Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

3. Section 455.654, Florida Statutes (1999), now at 456.053, Florida Statutes (2000), is known as the Patient Self-Referral Act of 1992. In general terms, this law prohibits health care providers from referring patients for the provision of designated health services and other health care items or services by an entity in which the health care provider is an investor, unless certain specified provisions of this law are satisfied. Among other potential sanctions, violations of this law by health care providers subject to the jurisdiction of this Board can result in disciplinary action by the Board. Section 456.053(5)(g), Florida Statutes.

4. Subsection 456.053(3)(o), Florida Statutes, defines the term "referral" broadly to include:

> 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.

5. Clearly Petitioner's sending of his own patients and the sending of patients by the other investor physicians described in the Petition, fall within this broad definition of the term "referral." However, subparagraph 456.053(3)(o)3., Florida Statutes (2000), provides several exceptions for specific orders, recommendations, or plans of care which do not constitute a referral by a health care provider. Of particular relevance to this Petition is the language set forth in subparagraph 456.053(3)(o)3.g., Florida Statutes (2000), which provides an exception for the referral of any patient for services provided by an ambulatory surgical center.

6. Although the overlapping ownership interests described in this Petition appear to be somewhat confusing, there is nothing in Florida law that prohibits physicians from sharing in the ownership of a management company. The facts set forth in the Petition do not suggest any inappropriate fee-splitting arrangement exists between Laser L.L.C. and and Petitioner as the owner of ASC. This Board has previously found inappropriate a fee-splitting arrangement between a management company responsible for negotiating, obtaining and maintaining managed care contracts, See, In re Bakarania, 20 FALR 395 (1998), but it has also found that a management contract containing fee-splitting arrangements that do not include such requirements is acceptable under Florida law. See, In re Rew, Rodgers, DOH-99-0977-DS-MQA (Filed August 25, 1999). Therefore, the only legal issue to be resolved is the application of

the self-referral prohibition set forth in section 456.053, Florida Statutes.

7. The exception from the definition of the term "referral" for the forwarding of any patient or for the establishment of a plan of care requiring services provided by an ASC, as set forth in subsection 456.053(3)(o)3.g., Florida Statutes (2000), exempts referrals for services provided by an ASC by a physician who is either an owner of or maintains an investment interest in an ASC from the prohibition against a physician referring a patient for health care services provided by an entity in which the referring physician is an investor or has an investment interest. Therefore, the Board finds that the referral of a patient by Petitioner or by the other physician investors in Laser L.L.C. to the ASC owned by Petitioner would not create a prohibited self-referral under section 456.053, Florida Statutes (2000).

8. This Final Order responds only to the specific facts set forth and specific questions set forth by Petitioners in the Petition for Declaratory Statement. The conclusions of the Board are with regard to the specific statutory provisions addressed and should not be interpreted as commenting on whether the proposed facts may or may not violate other provisions of Chapters 456 or 458, Florida Statutes, or other related obligations placed on physicians in Florida.

WHEREFORE, the Board hereby finds that under the specific facts of the Petition, as set forth above, the contractual arrangement contemplated by Petitioner is not prohibited by Section 456.053, Florida Statutes (2000).

DONE AND ORDERED this 13th day of December 2000.

Tanya Williams
for GEORGES A. EL-BAHRI
CHAIRMAN

NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE AGENCY FOR HEALTH CARE ADMINISTRATION AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to David W. Shoemaker, M.D., c/o Allen R. Grossman, Esquire, Gray, Harris & Robinson, P.A., Suite 250, 225 South Adams Street, Tallahassee, Florida 32301, and to M. Catherine Lannon, Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050, on or before 5:00 p.m., this _____ day of _____, 2000.

_____

AMENDED CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has been provided by certified mail to David W. Shoemaker, M.D., Center for Sight, 1360 E Venice Ave, Venice, FL 34292, Allen Grossman, Esquire, Gray, Harris & Robinson, PA, 225 S Adams St, Ste 250, Tallahassee, FL 32301, and interoffice delivery to M. Catherine Lannon, Assistant Attorney General, PL-01, The Capitol, Tallahassee, FL 32399-1050 at or before 5:00 p.m., this _____ day of _____, 2000.

_____

Arent Fox
ATTORNEYS AT LAW

MEDICINE BOARD
2000 MAY 25 PM 3:10

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Attorneys for the Petitioner

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK
DATE 5-15-00

PETITION FOR DECLARATORY STATEMENT BEFORE THE STATE OF FLORIDA BOARD OF MEDICINE

May 10, 2000
VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Florida Department of Health
Agency Clerk's Office
4052 Bald Cypress Way
Bin #A02
Tallahassee, FL 32399-1703

RECEIVED
JUN 9 2000

Dear Sir or Madam:

Pursuant to Fla. Stat. ch. 120.565 and Rule 28-105, Florida Administrative Code, David W. Shoemaker, M.D. ("Petitioner"), of 1360 East Venice Avenue, Venice, Florida 34292 (Tel: 941/488-2020, Fax: 941/484-2200) requests a declaratory statement to confirm that the proposed arrangement described in detail below would not constitute prohibited activity under Fla. Stat. ch. 455.654 (the "Patient Self-Referral Act of 1992").[1]

Patient Self-Referral Act of 1992

Section 455.654(5)(b) of Florida Statutes prohibits a health care provider from referring a patient for the provision of any non-designated item or service to an entity in which the health care provider is an investor. However, according to Section 455.654(3)(o)(3)(g), an order, recommendation, or plan of care "by a health care provider for services provided by an ambulatory surgical center" shall not constitute a referral by a health care provider.

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[1] Section 455.654(5)(b)(4) states that "each board . . . 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."

According to Section 455.654(5)(b)(2), there is also an exception for investment interests that meet the following requirements:

(i) 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;

(ii) 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 referrals;

(iii) 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;

(iv) 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;

(v) The entity does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity if the investor uses any part of such loan to obtain the investment interest; and

(vi) 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 by that investor.

Proposed Arrangement

Petitioner is a board-certified ophthalmologist who wishes to facilitate the establishment of a new corporate entity, likely a limited liability company ("Laser Company"), to provide refractive laser equipment and services to an ambulatory surgical center. Laser Company will be owned 40% by a group of physician investors (including Petitioner), and 60% by Laser & Surgical Services at Center for Sight, LLC ("ASC LLC"), a limited liability company that owns and operates an ambulatory surgical center ("ASC"). ASC LLC is composed of two members: (i) the Petitioner, individually, as a 1% owner; and (ii) Shoemaker II Family Limited Partnership, consisting of partners that are trusts created by Petitioner and/or his wife and a corporate entity in which Petitioner and his wife are sole shareholders, as a 99% owner. The physician investors may, at times, refer patients to one another for eye care services, including laser procedures performed at the ASC.

Laser Company will lease staff from the Practice and will assume the lease for an excimer laser currently held by one of Petitioner's medical practices ("Practice"). Both transactions between Practice and Laser Company will be structured to be consistent with fair market value.

Laser Company will make available to the ASC equipment, supplies, and staffing services necessary for the performance of laser procedures. Laser Company may also provide certain administrative services to the ASC, including billing and collection, marketing, and other related services. Laser Company intends to bill the ASC on a per-case basis for the equipment, supplies, staff, and administrative services. It is anticipated that the pricing will be on a sliding scale with the cost per case decreasing as the volume of laser procedures increases.

ASC will likely collect payments for professional and facility services and forward the professional collections to the surgeons who perform procedures at its facility. In the event that the ASC decides to hire Laser Company to provide the billing and collection services, Laser Company will then forward the facility component to the ASC offset by the amount of Laser Company's management/equipment fee.

Analysis

We believe that the Patient Self-Referral Act will not be implicated by the proposed arrangement because Section 455.654(3)(o)(3)(g) states that an order, recommendation, or plan of care "by a health care provider for services provided by an ambulatory surgical center" shall not constitute a referral by a health care provider. Under the proposed scenario, the optometrist and physician investors will be referring patients to the ASC for which Laser Company will be providing staff, equipment, and administrative services. Laser Company will not be an independent provider of services, but simply a contractor of services to the ASC.

Even if one were to take the view that the proposed arrangement will cause a separate referral to Laser Company, the arrangement will still be structured in a manner consistent with the investment exception described above. The terms under which the investment interest will be offered will not relate to whether such investors are in a position to make referrals or the previous or expected volume of referrals of such investors. There will be no requirement to make referrals as a condition for becoming or remaining an investor, and the entity will not loan or guarantee funds to potential investors. The return on investment will be directly proportional to the amounts invested by each investor. Further, only 40% of the interests will be held directly by investors who are in a position to make referrals to the ASC. We recognize, however, that with respect to Petitioner's interests in ASC LLC, he may be in a position to indirectly refer to the ASC.

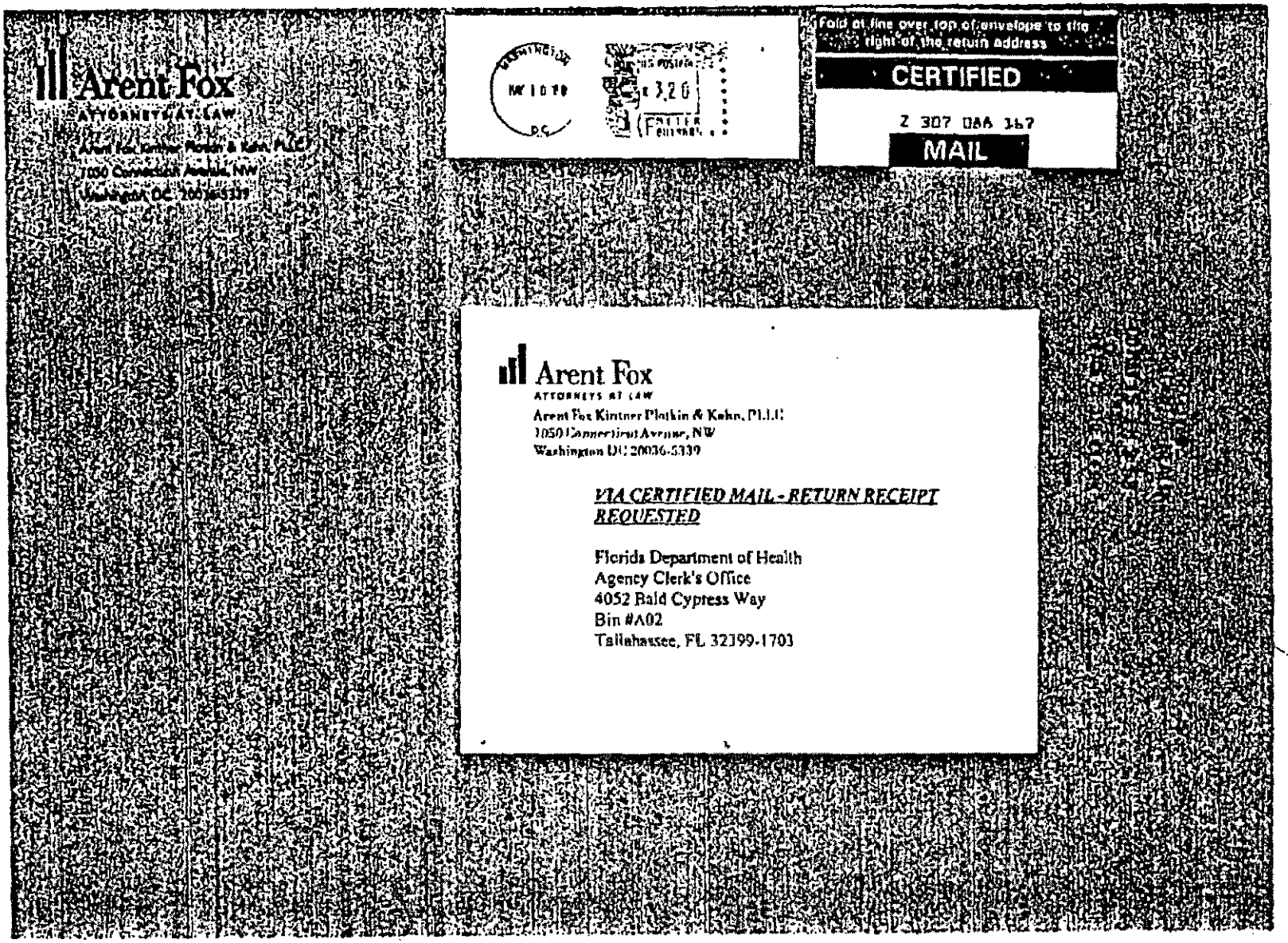
While we believe that the Patient Self-Referral Act will not be implicated by the proposed arrangement, Petitioner seeks a declaratory statement confirming this position. The parties look forward to the possibility of forming this new entity as soon as possible and would appreciate your guidance on this proposed arrangement. Please contact us with any comments or questions.

Sincerely,

Darren T. Binder

Darren T. Binder

cc: David W. Shoemaker, M.D.



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CERTIFIED

Z 307 088 367

MAIL

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VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Florida Department of Health
Agency Clerk's Office
4052 Bald Cypress Way
Bin #A02
Tallahassee, FL 32399-1703

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. 455.701.

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.

Note.—Former s. 455.236.

455.654 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 over utilization 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 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.

i. By a urologist for lithotripsy services.

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.

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

l. By a nephrologist for renal dialysis services and supplies.

(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 form 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 which must provide at least 75 percent of his professional services to the group. Alternatively, the group must be incorporated under chapter 617, Florida Statutes, and must be exempt under the provisions of the Internal Revenue Code 501 (c) (3) 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. of this subsection, 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 s. 455.654 (4) (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 s. 455.654 (4) (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. 455.701.

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.

Note.—Former s. 455.236.