SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 2438

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Latvala

SUBJECT: The Patient Self-Referral Act of 1992

DATE: April 21, 1999 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Carter/Munroe	Wilson	HC	Favorable/CS
2.				
3.				
4.				
5.				

I. Summary:

Committee Substitute for Senate Bill 2438 amends the Patient Self-Referral Act of 1992 by defining additional terms used in the Act, including: "diagnostic imaging services," "direct supervision," "outside referral for diagnostic imaging services," "patient of a group practice," "present in the office suite," and "sole provider." The definition of the term "referral" is revised to modify the group practice exception to allow, effective July 1, 1999, certain specified physicians to refer a patient to a sole practitioner or a group practice that is authorized to receive up to 15 percent of their patients for diagnostic imaging services, excluding radiation therapy services, from outside referrals subject to some restrictions. Despite prohibitions against certain referrals, the bill authorizes group practices and sole practitioners to accept up to 25 percent of their patients from outside referrals for diagnostic imaging services upon such time as the Agency for Health Care Administration (AHCA or agency) adopts and implements rules recommended as a result of a study required in the bill. The bill amends the Act to provide requirements for a sole practitioner or a group practice to accept outside referrals for diagnostic imaging services delineating: (1) who may deliver such services, (2) who must hold the equity in the group practice or sole provider's practice, (3) the characteristics of management of such practices, (4) billing for services, (5) provision of diagnostic imaging services to Medicaid recipients by the affected providers, and (6) reporting of referrals accepted and total number of patients receiving diagnostic imaging services from the sole practitioner or the group practice accepting referrals as provided in the bill. Group practices providing diagnostic imaging services must be registered with AHCA by December 31, 1999, regardless of who owns the group practice.

The bill directs AHCA to study the need for quality-of-care standards applicable to group practices, hospitals, and health systems that provide diagnostic imaging services, addressing certain specified issues, though expressly not limited to such issues, and to report its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 15, 2000. The agency is authorized to convene a technical assistance panel comprised of representatives of the various parties of interest to the provision of diagnostic imaging services, including representation of the public. The agency, in conjunction with the

Medicaid Fraud Division of the Office of the Attorney General, must conduct a detailed study and analysis of clinical laboratory services for kidney dialysis patients. The agency must submit a report of its findings to the Legislature by February 1, 2000.

The contingency in the effective date of the legislation enacted during the 1998 legislative Session that repealed the Public Medical Assistance Trust Fund assessment on freestanding radiation therapy centers and exempted hospital outpatient radiation therapy centers from the same assessment is deleted from law. By deleting the contingency, chapter 98-192, *Laws of Florida*, has an effective date of July 1, 1998.

This bill amends s. 455.654, Florida Statutes, 1998 Supplement, and s. 4 of chapter 98-192, *Laws of Florida*. The bill creates four sections not assigned to the *Florida Statutes*.

II. Present Situation:

Section 455.654, F.S., 1998 Supplement, is the “Patient Self-Referral Act of 1992" (Patient Self-Referral Act or Act). The Act *purports* to regulate the referral of patients by a health care provider for specified services or treatments when a health care provider has a financial interest in the service or treatment provided. The Act prohibits health care providers from referring patients for the provision of certain designated health services to an entity in which the health care provider is an investor.

The Act provides definitions for purposes of its requirements relating to financial arrangements between referring health care providers and providers of health care services. The Act defines “designated health services” to mean clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services. “Referral” is defined to mean any referral of a patient by a health provider for health care services which includes: the forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies a designated health service or any other health care item or service; or the request or establishment of a plan of care by a health care provider, which includes the provision of a designated health service or other health care item or service.

The Patient Self-Referral Act codifies exceptions to the prohibited referrals under the Act which include any order, recommendation, or plan of care by:

- a radiologist for diagnostic-imaging services;
- a physician specializing in the provision of radiation therapy services for such services;
- a medical oncologist for drugs and solutions to be prepared and administered intravenously to such oncologist’s patient, as well a supplies and equipment used in connection with treating such a patient for cancer and related complications;
- a cardiologist for cardiac catheterization services;
- 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;
- a health care provider for services provided by an ambulatory surgical center licensed under chapter 395, F.S.;

- a health care provider for diagnostic clinical laboratory services where such services are directly related to renal dialysis;
- a urologist for lithotripsy services;
- a dentist for dental services performed by an employee of or a health care provider who is an independent contractor with the dentist or group practice of which the dentist is a member;
- a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice; and
- a nephrologist for renal dialysis services and supplies.

The Act also provides a group practice exception to the prohibited referrals in s. 455.654(3)(k)3.f., F.S., 1998 Supplement. The group practice exception prohibits referrals through any order, recommendation, or plan of care by a health care provider who is the sole provider or member of a group practice for designated 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.

The Agency for Health Care Administration (AHCA or agency) challenged an order of the Board of Medicine on a petition for a declaratory statement regarding the interpretation of the Patient Self-Referral Act in *Agency for Health Care Administration v. Wingo*, 697 So.2d 1231 (1st DCA June 1997). The First District Court of Appeal reviewed the board's declaratory statement involving a group practice that had purchased a magnetic resonance imaging system (MRI) for use by the practice's patients. Under the facts, the practice expected some patient referrals for MRI services from physicians outside of the group practice who had no investment interest in the group practice. The board's order stated that the group practice could accept MRI referrals from physicians outside of the group to supplement the group practice's utilization and still maintain the "group practice exception" to the Patient Self-Referral Act. In its order, the board accepted the group practice's argument that it should be treated differently under the exception because it was accepting patients rather than referring them.

The First District Court of Appeal narrowly construed the "group practice exception" for certain prohibited patient referrals by holding that a group practice that accepts any outside referrals that involves use of the group practice's equipment or facilities loses its privilege to the "group practice exception." The court found that a group practice may lawfully provide MRI services to its own patients *only* if it refrains from accepting patients referred from physicians who are not a part of the group practice.

III. Effect of Proposed Changes:

Section 1. Amends section 455.654, F.S., 1998 Supplement, relating to financial arrangements from referring health care providers to providers of health care services, to:

- Revise subsection (3), providing definitions used in the Patient Self-Referral Act, to define the terms "diagnostic imaging services," "direct supervision," "outside referral for diagnostic imaging services," "patient of a group practice" or "patient of a sole provider," "present in the office suite," and "sole provider." The definition of the term "referral" is revised to expand the list of orders, recommendations, and plans *excluded from the term* to include,

effective July 1, 1999, referrals for diagnostic imaging services, excluding radiation therapy services. Such referrals are those *received from* a state-licensed allopathic, osteopathic, chiropractic, or podiatric physician, if the referring physician has no investment interest in the provider to which he or she refers the patient, to a sole practitioner or a group practice that bills both the *technical and the professional fee* for, or on behalf of, the patient. The group practice or sole practitioner are restricted to accepting no more than 15 percent *of their patients receiving diagnostic imaging services from outside referrals*, excluding radiation therapy services.

- Add a new subsection (4), providing requirements for accepting outside referrals for diagnostic imaging, to require a group practice or sole practitioner accepting outside referrals for diagnostic imaging services to comply with the following specified conditions:

  - the services must be provided exclusively by a group practice physician or a full-time or part-time employee of the group practice or of the sole provider's practice;
  - all equity in the group practice or sole provider's practice must be held by the physicians comprising the group practice or the sole provider's practice and each must provide at least 75 percent of his professional services to the group;
  - the group practice or sole provider may not be managed by the same entity, or a related entity, that owns, manages, or otherwise has any interest in the group practice or sole provider who refers the patient;
  - the group practice or sole provider 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;
  - a group practice or sole provider that has a Medicaid provider agreement with AHCA 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; and
  - group practices and sole practitioners accepting outside referrals for diagnostic imaging must submit an annual report to AHCA providing the number of such referrals accepted and the total number of *all* patients receiving diagnostic imaging services--direct referrals and outside referrals.

Any referrals by an authorized group practice or a sole practitioner, as provided under this subsection, in violation of this subsection or in excess of the 15 percent volume cap established under subparagraph 455.654(3)(o)f., F.S., as created in this bill, subjects such group practice or sole practitioner to penalties established for violation of the Patient Self-Referral Act of 1992 under subsection 455.654(5), F.S., 1998 Supplement. Such penalties include refund of billings collected in violation of s. 455.654, F.S., 1998 Supplement; liability for a civil penalty of up to $15,000 imposed by the Board of Medicine or the Board of Osteopathic Medicine; liability for a civil penalty of up to $100,000 for referral arrangement or schemes designed to circumvent the Act; or disciplinary action by the appropriate regulatory board.

Section 2. Requires AHCA to conduct a detailed study and analysis of issues relating to the need for quality-of-care standards applicable to group practices providing diagnostic imaging services.

At a minimum, AHCA is directed to include review of the following issues during its study: (1) the parameters of quality of care; (2) the need for periodic inspection of diagnostic imaging sites; (3) evaluation of the usefulness of requiring group practices providing diagnostic imaging services to participate in nationally recognized accreditation organizations for purposes of enhancing quality assurance processes; and (4) assessing how group practices that provide diagnostic imaging services ensure appropriate utilization of services in order to prevent overutilization of such services. The agency is authorized to convene a technical assistance panel for purposes of the study comprised of representatives of group practices providing diagnostic imaging services; group practices, generally; various professional organizations representing providers and hospitals; and representatives of the public. The agency must submit a report of its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 15, 2000.

Section 3. Provides that AHCA must require all group practices providing diagnostic imaging services, regardless of ownership, to register by December 31, 1999. Information that must be submitted for registration includes: (1) the medical specialty of each physician; (2) address and phone number of the group; (3) UPIN number for the group and each group number; and (4) Medicare, Medicaid, and commercial billing numbers for the group.

Section 4. Provides that irrespective of s. 455.564, F.S., 1998 Supplement, relating to general licensure requirements for certain health care professionals, when AHCA adopts and implements rules recommended by the study that is required under section 2 of the bill, group practices and sole practitioners are authorized to accept up to 25 percent of their patients from outside referrals for diagnostic imaging.

Section 5. The Agency for Health Care Administration is directed to conduct a detailed study and analysis, in conjunction with the Medicaid Fraud Division of the Office of the Attorney General, of clinical laboratory services for kidney dialysis patients specific to Florida. The agency must submit a report of its findings and recommendations to the Legislature by February 1, 2000. At a minimum, the study must include an analysis of: (1) the past and present utilization rates of clinical laboratory services for dialysis patients; (2) financial arrangements among kidney dialysis centers, their medical directors, any business relationships and affiliations with clinical laboratories, and any self-referral to clinical laboratories; (3) the quality and responsiveness of clinical laboratory services for dialysis patients in Florida; and (4) the average annual revenue for dialysis patients for clinical laboratory services for the past 10 years.

Section 6. Modifies the effective date of chapter 98-192, Laws of Florida, to remove language that makes amendments to ss. 395.701 and 395.7015, F.S., 1998 Supplement, relating to Public Medical Assistance Trust Fund assessments on hospitals and certain other health care providers, effective *contingent* upon AHCA receiving written confirmation from the federal Health Care Financing Administration that the changes in such amendments *will not adversely affect the use of the remaining assessments as state match for the state's Medicaid program*.

Section 7. Provides an effective date of July 1, 1999.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

There is some *potential* that this bill could increase assessments deposited as revenue into the Public Medical Assistance Trust Fund (PMATF). Such an increase could result if health care providers that provide diagnostic imaging services that are subject to the regulatory tax collected to fund the PMATF experience an increase in business volume. However, since the assessment is based on the net operating revenue of the assessed entity, if the net operating revenues of freestanding providers of diagnostic imaging services are substantially less than such revenues of hospital providers of diagnostic imaging services overall revenue collected and deposited into the PMATF may be reduced.

The deletion of the contingency in the effective date of chapter 98-192, *Laws of Florida*, as provided in section 6 of the bill, may have the effect of repealing the PMATF assessment for freestanding radiation therapy providers and exempting hospital outpatient providers of radiation therapy services *effective July 1, 1998*. If this is correct, this may entitle affected providers to a refund of monies AHCA collected as PMATF assessments for 1998.

B. Private Sector Impact:

Though it is impossible to quantify with a real sense of accuracy, this bill will have a fiscal impact on physicians and hospitals that provide diagnostic imaging services. Therefore, conceivably, the bill may have the effect of shifting some insurance reimbursements and public-sector payments for diagnostic imaging services between competing segments of the health care provider community.

The consumer (i.e., insurers, individuals paying out-of-pocket, as well as the Medicaid and Medicare programs, and other public-sector payers) impact, in terms of costs of services as a consequence of the changes made in the bill, is indeterminable.

C. Government Sector Impact:

The most relevant government sector impact to the State would be to the Medicaid program. The Agency for Health Care Administration indicates that any fiscal impact to the Medicaid program resulting from the provisions of the bill would be indirect and as a consequence of "shifts" in the marketplace provision of services. What the impact may be is indeterminable to any reasonable degree of certainty, however.

Both hospital outpatient facilities and freestanding facilities are subject to the PMATF assessment. The agency stated that if the expansion of the list of orders, recommendations, or plans of care that do not constitute a referral results in a substantial shift of provision of care from *hospital outpatient facilities* to more *freestanding facilities*, there could be an impact on revenues to the PMATF that is used to fund a portion of Medicaid expenditures as a consequence of the difference, if any, in the net operating revenue that the freestanding facilities generate relative to the hospital outpatient facilities. A regulatory tax of 1.5 percent of net operating revenues is assessed on hospitals, ambulatory surgical centers, clinical laboratories, freestanding radiation therapy centers, and diagnostic imaging centers. To the extent that the changes to law, as provided in the bill, result in lower total assessments due to differences in net operating revenues of the providers of diagnostic imaging services, revenues to the PMATF could be diminished. Consequently, a larger proportion of indigent health care costs may have to be paid by governmental entities.

VI. Technical Deficiencies:

On page 7, lines 4 and 5, the introductory clause of the subparagraph, in existing law, should be modified to make a more grammatically correct and readable beginning for the existing sub-subparagraphs as well as the new ones added in the bill. It may be revised to read: *The following orders, recommendations, or plans of care shall not constitute a referral ~~by a health care provider~~:*

On page 9, line 23, the reference to physicians and the percentage of their professional services that they must provide to a group practice of which they are a member should be revised and state in a gender-balanced manner, thus, the revised line would read: <u>least 75 percent of his or her professional services to the group.</u>

On page 10, line 22, the cross reference to subparagraph (a)2., requiring that a physician holding an equity position in a group practice *must provide at least 75 percent of his professional services to the group*, appears to be incorrect. The error results because, read in context, the reference seems to be to the permissive volume of outside referrals a group practice or sole practitioner may accept, which is stated in two different provisions in the bill as two different percentage caps. First, in paragraph 455.654(3)(o)3.f., F.S., as provided in the bill on page 8, line 4, as a 15 percent cap, and, second, in section 4 of the bill on page 15, line 29, as a 25 percent cap.

On page 15, lines 9 and 10, an apparently redundant reference is made in listing representative participants on the technical assistance panel that AHCA is authorized to convene by stating: <u>group practices, group practices generally</u>.

On page 15, line 26, the cross reference to s. 455.564, F.S., 1998 Supplement, appears in error. That provision relates to general licensure requirements for health care professionals as administered by the Department of Health, and, given the context in which this cross reference is used--authorizing group practices and sole practitioners to accept up to 25 percent of their patients from outside referrals for diagnostic imaging *upon such time as* AHCA adopts and implements rules recommended by the study required under section 2 of the bill--the correct cross reference should be s. 455.654, F.S., 1998 Supplement.

On page 16, line 2, the word “Division” should be “Unit.”

VII. Related Issues:

Section 5 of the bill apparently involves an issue currently in litigation in a Florida court.

VIII. Amendments:

None.