

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 108

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Financial Arrangements Between Referring Health Care Providers and Providers of Health Care Services

DATE: November 17, 2015 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Fav/CS
2.	_____	_____	BI	_____
3.	_____	_____	FP	_____

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 108 amends s. 456.053, F.S., the Patient Self-Referral Act (Act), to allow physicians to refer patients for clinical laboratory services incidental to renal dialysis to providers in which the physician has an investment interest. Specifically, the bill:

- Allows all physicians to refer patients for clinical lab services incidental to renal dialysis to a provider in which the physician has an investment interest if the physician’s investment interest falls within an exception allowed for non-designated health services; and
- Allows nephrologists to refer patients for clinical lab services incidental to renal dialysis to a provider in which the nephrologist has an investment interest regardless of type of investment interest the nephrologist may have

The bill also makes technical and conforming changes including exempting investment interests in rural providers of such services from the definition of “investment interest” under the act. This change is made to conform with the removal of such services from the definition of “designated health services.”

The act takes effect upon becoming a law.

II. Present Situation:

The Patient Self-Referral Act of 1992

Section 456.053, F.S., entitled the “Patient Self-Referral Act of 1992” was enacted by the Legislature to safeguard the people of Florida from unnecessary and costly health care expenditures while providing guidance to health care providers on prohibited patient referrals.¹

A health care provider to whom the Act applies is a physician licensed under ch. 458, 459, 460, or 461, F.S., or any health care provider licensed under ch. 463 or 466, F.S. Allopathic, osteopathic, chiropractic, and podiatric physicians, certified optometrists, and dentists are health care providers under the Act.

The Act has differing limitations and prohibitions on patient referrals depending on the type of health care service to be provided as follows:

- A health care provider may not refer a patient for the provision of designated health services² to an entity in which the health care provider is an investor³ or has an investment interest.^{4,5}
- A health care provider may not refer a patient for the provision of any other health care services or items (non-designated health services) to an entity in which the health care provider is an investor unless:⁶
 - For entities whose shares are publicly traded:
 - The provider’s investment interest is in registered securities purchased over a national exchange or over-the-counter market; and
 - The entity’s total assets at the end of the last fiscal quarter exceed \$50 million;
 - For entities whose shares are not publicly traded:
 - No more than 50 percent of the value of the investment interests are held by investors in a position to make referrals to the entity;
 - The terms of an investment interest offered to an investor are the same regardless of whether the investor is in a position to make referrals;

¹ Section 456.053(2), F.S.

² Section 456.053(3)(c), F.S., defines “designated health services” as clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services.³ Section 456.053(3)(l), F.S., defines “investor” as 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.

³ Section 456.053(3)(l), F.S., defines “investor” as 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.

⁴ Section 456.053(3)(k), F.S., defines “investment interest” to include 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 instrument. Certain investment interests are excepted from the definition including an investment interest in a sole provider of health care services in a rural area; an investment interest in the form of certain notes, bonds, debentures, or other debt instruments that matured prior to Oct. 1, 1996; an investment interest in real property resulting in a landlord-tenant relationship between the entity and the referring healthcare provider unless the rent is determined by the volume of referrals; and an investment interest in an entity which owns or leases and operates a hospital or nursing home.

⁵ Section 456.053(5)(a), F.S. Offices providing radiation therapy services are exempt from these requirements if they were in business before April 1, 1991. (*See* s. 456.053(5)(i), F.S.).

⁶ Section 456.053(5)(b), F.S.

- The terms offered to an investor are not related to the previous or expected volume of referrals; and
- There is no requirement that an investor refer patients to the entity as a condition for becoming or remaining an investor.
- Entities accepting outside referrals for diagnostic imaging must meet additional conditions including conditions for the physician make-up of the solo or group practice as well as physician performance of diagnostic imaging services, conditions on billing practices, restrictions on contracting with outside providers, and conditions on reporting accepted outside referrals to the Agency for Health Care Administration (AHCA).⁷

A health care provider who has an investment interest in an entity to which he or she refers a patient must disclose such interest to the patient on a written form that details the patient's right to obtain the services elsewhere along with at least two alternative sources from which the patient could receive the services.⁸

A health care provider found to have violated the Act could be subject to one or more disciplinary actions or penalties including:

- A penalty of up to \$100,000 for each arrangement if a health care provider or other entity enters into an arrangement that has the principal purpose of assuring referrals between the provider and the entity.⁹
- Discipline by his or her appropriate board and hospitals are subject to penalties imposed by the AHCA.¹⁰
- Being charged with a first degree misdemeanor and subject to additional penalties and disciplinary action by his or her respective board if a health care provider fails to comply with the notice provisions of the Act and s. 456.052, F.S.¹¹

A claim for payment for a service provided pursuant to a referral prohibited by the Act may not be made and any such payments received must be refunded. Additionally, any person who knows or should know that such a claim is prohibited and who presents or causes to be presented such a claim, is subject to a fine of up to \$15,000 per service to be imposed and collected by that person's regulatory board.¹²

The Federal Stark Law

Generally similar to the Act, the federal Stark Law¹³ (Stark) prohibits physicians from referring patients to receive designated health services that are payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies.¹⁴ Under Stark, designated health services include:

⁷ Section 456.053(4), F.S.

⁸ Sections 456.053(5)(j) and 456.052, F.S.

⁹ Section 456.053(5)(f), F.S.

¹⁰ Section 456.053(5)(g), F.S.

¹¹ Section 456.052(3), F.S.

¹² Section 456.053(5)(c)-(e), F.S.

¹³ 42 U.S.C. s. 1395nn.

¹⁴ U.S. Dept. of Health & Human Services, Office of the Inspector General: *A Roadmap for New Physicians: Fraud and Abuse Laws*, available at <http://oig.hhs.gov/compliance/physician-education/01laws.asp>, (last visited Nov. 17, 2015).

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.¹⁵

The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. Stark prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Penalties for physicians who violate Stark include fines as well as exclusion from participation in the Federal health care programs.¹⁶

Exceptions to the Stark's self-referral prohibitions include:

- Exceptions for certain services including:
 - Most referrals of a patient for physician's services and in-office ancillary services provided by the same physician or another physician in the same group practice; and
 - Referrals for services furnished by an organization that has a contract with a health maintenance organization or a prepaid health plan.¹⁷
- Exceptions related to ownership or investment interests including:
 - Ownership of investment securities that are publically traded and held in a corporation with equity exceeding \$75 million on average during the previous three fiscal years and which were purchased on terms generally available to the public; and
 - Ownership of shares in an investment company if the company has total assets exceeding \$75 million on average during the previous three fiscal years.¹⁸
 - Ownership of certain hospitals including hospitals in Puerto Rico, in rural areas, and certain hospitals in which the referring physician is authorized to perform services.¹⁹
- Exceptions related to other compensation arrangements including:
 - The rental of office space or equipment with terms that are consistent with fair market value and without consideration of any past or future referrals made between the parties;
 - Bona fide employment relationships with remuneration that does not take into account the volume or value of referrals by the referring physician;
 - Personal services arrangements with terms that do not exceed fair market value and do not take into account the volume or value of any referrals or other business generated between the parties;

¹⁵ 42 U.S.C. s. 1395nn(h)(6). When compared to Florida law, it can be seen that the list of designated health services under Stark includes the services listed as designated health services under the Act but also includes additional services not included in Florida law.

¹⁶ See supra note 15.

¹⁷ 42 U.S.C. s. 1395nn(b).

¹⁸ 42 U.S.C. s. 1395nn(c).

¹⁹ 42 U.S.C. s. 1395nn(d).

- Physician incentive plans if no specific payment is made to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity;
- Remuneration provided by a hospital to a physician that is unrelated to designated health services;
- Physician recruitment bonuses paid by a hospital that do not take into account the volume or value of referrals;
- Certain isolated transactions;
- Certain group practice arrangements made with hospitals that began before December 19, 1989; and
- Payments made by a physician for laboratory services or other items or services if paid at fair market value.²⁰

Additional Restrictions on Agreements between Referring Health Care Providers and Providers of Health Care Services

Federal and State Anti-Kickback Statutes

Both Florida and Federal law include a prohibition on providing any sort of kickback for the referral of patients from a health care provider to a licensed facility. Section 395.0185, F.S., prohibits any person from paying a commission, bonus, kickback, or rebate or engaging in any form of split-fee arrangement with a physician, surgeon, organization, or person for patients referred to a licensed facility. The AHCA is required to enforce the provisions of the law and, if the violator is not licensed by the AHCA, the law authorizes the AHCA to impose a fine of up to \$1,000 nonetheless, and to recommend disciplinary action to the appropriate licensing board. Section 456.054, F.S., prohibits a health care provider or provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients.²¹

Federal law also prohibits such payments for the referral of an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made under a Federal health care program.²² Violating the federal anti-kickback statute makes the violator guilty of a felony which is punishable by a fine of up to \$25,000 or up to 5 years in prison. However, there are several exceptions to the federal statute including, but not limited to:

- Discounts properly disclosed and appropriately reflected in the costs claimed and charges made by the provider or entity;
- Payments between employers and employees for employment in the provision of covered items or services;
- Certain amounts paid to vendors;
- Waivers of co-insurance; and
- The waiver of any cost-sharing provisions by a pharmacy.

²⁰ 42 U.S.C. s. 1395nn(e).

²¹ Violations of this section are considered patient brokering and are punishable as provided in s. 817.505, F.S., which can include criminal penalties (felony of the third degree) and other civil, administrative, or criminal penalties.

²² 42 U.S.C. s. 1320a-7b(b)(2)(A).

Anti-Trust Laws

Additionally, both Florida and Federal law prohibit price-fixing and unfair trade practices which may be applicable to certain relationships between referring health care providers and providers of health care services. The Florida Deceptive and Unfair Trade Practices Act²³ generally prohibits unfair methods of competition, as well as deceptive acts or practices, in the conduct of trade or commerce. Also, Federal anti-trust laws, including the Sherman Act, generally prohibit unreasonable restraints on fair trade created by contract, combination, or conspiracy.²⁴

Clinical Laboratory Services Incidental to Renal Dialysis

Renal dialysis is a treatment used to replace the work of failing kidneys. There are two types of dialysis, hemodialysis and peritoneal dialysis,²⁵ which both filter the body's blood to rid it of harmful wastes, extra salt, and water. Dialysis can be performed in a hospital, in a dialysis unit that is not part of a hospital, or at home. Although dialysis is expensive, Medicare pays 80 percent of the costs for most people.²⁶ Additionally, as of January 1, 2011, Medicare requires that all services associated with the renal dialysis be paid in a bundle payment with the dialysis, including laboratory services.²⁷ Currently such laboratory services fall under the definition of "designated health services" and a physician may not refer a patient for such services to a provider in which the physician has an investment interest without violating the Patient Self-Referral Act.²⁸ Laboratory services that typically are bundled with renal dialysis include a basic metabolic panel, an electrolyte panel, a renal function panel, and numerous others.²⁹

III. Effect of Proposed Changes:

CS/SB 108 amends s. 456.053, F.S., the Patient Self-Referral Act, to allow physicians to refer patients for clinical laboratory services incidental to renal dialysis to providers in which the physician has an investment interest. Specifically, the bill:

- Creates an exception to the definition of "designated health services"³⁰ for clinical laboratory services incidental to renal dialysis. This allows all physicians who refer patients for clinical lab services incidental to renal dialysis to refer such patients to a provider in which the physician has an investment interest if the investment interest falls within the exceptions allowed for non-designated health services;³¹ and
- Exempts referrals of patients by a nephrologist for such services from the definition of "referral" which allows nephrologists to refer patients for clinical lab services incidental to

²³ Section 501.204, F.S.

²⁴ Federal Trade Commission, *The Antitrust Laws*, available at: <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws>, (last visited Nov. 17, 2015).

²⁵ For an explanation of the two types of dialysis, see <https://www.kidney.org/atoz/content/dialysisinfo>. (Last visited Nov. 17, 2015).

²⁶ Id.

²⁷ End Stage Renal Disease Prospective Payment System, p. 5, available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage-Renal-Disease-Prospective-Payment-System-ICN905143.pdf> (last visited Nov. 17, 2015).

²⁸ See supra note 2.

²⁹ For a full list see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/Consolidated-Billing-ESRD-PPS-2015-CR-9127.pdf> (Last visited Nov. 17, 2015).

³⁰ See supra note 2.

³¹ These exceptions are discussed on page two of the analysis.

renal dialysis to a provider in which the nephrologist has an investment interest regardless of type of investment interest the nephrologist may have.

These referrals remain subject to the limitations placed on patient self-referral by the federal Stark Law.

The bill also makes technical and conforming changes including exempting investment interests in the sole provider of clinical laboratory services incidental to renal dialysis in a rural area from the definition of “investment interest” under the act. This change is made to conform with the removal of such services from the definition of “designated health services.”

The act takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 108 may have a positive fiscal impact on prescribers and providers of clinical laboratory services incidental to renal dialysis who are currently restricted from referring patients, or accepting patient referrals, if an investment interest exists.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 456.053 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on November 17, 2015:

The CS amends SB 108 to replace the provisions of the original bill with new provisions allowing physicians to refer patients for clinical laboratory services incidental to renal dialysis to providers in which they have certain types of investment interests. These new provisions include:

- Creating an exception to the definition of “designated health services” for clinical laboratory services incidental to renal dialysis;
- Exempting referrals of patients by a nephrologist for such services from the definition of “referral”; and
- Exempting investment interests in rural providers of such services from the definition of “investment interest” under the act.

The CS/SB 108 also makes technical and conforming changes.

- B. **Amendments:**

None.