

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 601 Referral of Patients by Health Care Providers

SPONSOR(S): Steele

TIED BILLS: IDEN./SIM. BILLS: SB 768

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---------------------------------------|-----------|---------|--|
| 1) Healthcare Regulation Subcommittee | 17 Y, 0 N | Poche | McElroy |
| 2) Health & Human Services Committee | 20 Y, 0 N | Poche | Calamas |

SUMMARY ANALYSIS

Healthcare providers routinely refer patients to other healthcare providers if more specialized care is required. The Florida Patient Self-Referral Act of 1992 prohibits a Florida health care provider from referring a patient to an entity in which the health care provider holds an investment interest. There are limited exceptions to this prohibition, including an exception which allows health care providers to refer patients to hospitals in which the health care provider holds an investment interest.

The federal Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" (DHS) payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements.

HB 601 amends s. 456.053, F.S., regulating financial arrangements between referring health care providers and health care service providers, to alter a safe harbor provision for permitted referrals from a health care provider to another provider for DHS that solely serves patients of the referring health care provider. The bill removes the direct supervision requirement and the requirement that the physician be present in the office suite, allowing general supervision of such services from locations outside of the office where the services are provided.

The bill allows self-referring health care providers to avoid the cost of having a physician present while health care services are provided. The change in state law also aligns with federal Stark law provisions regarding self-referrals by a health care provider to another provider in which the referring physician has a financial or other pecuniary interest.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2023.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Federal Physician Self-Referral Law – Stark Law

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies.¹ Financial relationships include both ownership/investment interests and compensation arrangements.² For example, if a physician invests in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or that physician may not refer patients to the facility and the entity may not bill for the referred imaging services.

Under the Stark law, "designated health services" (DHS) are:

- Clinical laboratory services;
- Physical therapy, occupational therapy, and outpatient speech-language pathology services;
- Radiology and certain other imaging services;
- Radiation therapy services and supplies;
- DME 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.³

When enacted in 1989, the Stark law applied only to physician referrals for clinical laboratory services.⁴ In 1993 and 1994, Congress expanded the prohibition to additional DHS and applied certain aspects of the physician self-referral law to the Medicaid program.⁵ In 1997, Congress added a provision permitting the Secretary of the federal Department of Health and Human Services to issue written advisory opinions concerning whether a referral relating to DHS, other than clinical laboratory services, is prohibited under the law.⁶ In addition, in 2003 Congress authorized the Secretary to promulgate an exception to the physician self-referral prohibition for certain arrangements in which the physician receives non-monetary remuneration that is necessary and used solely to receive and transmit electronic prescription information and established a temporary moratorium on physician referrals to certain specialty hospitals in which the referring physician has an ownership or investment interest.⁷

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

Federal Anti-Kickback Statute (AKS)

¹ 42 USC s. 1395nn

² Id.

³ Id.

⁴ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare, *Physician Self-Referral*, available at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index?redirect=/physicianselfreferral/> (last viewed on March 29, 2023).

⁵ Id.

⁶ Id.

⁷ Id.

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the federal health care programs., including, for example, drugs, supplies, or health care services for Medicare or Medicaid patients.⁸ Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.⁹ The statute covers the payers of kickbacks-those who offer or pay remuneration- as well as the recipients of kickbacks-those who solicit or receive remuneration.¹⁰ Each party's intent is a key element of their liability under the AKS.¹¹

Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the federal health care programs. Under the Civil Monetary Penalties Law¹², physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.¹³

Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution.¹⁴ To be protected by a safe harbor, an arrangement must satisfy all of its requirements.¹⁵ Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to bona fide employees.¹⁶

Besides the AKS, the beneficiary inducement statute also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.¹⁷

Florida Patient Self-Referral Act of 1992

The Patient Self-Referral Act of 1992 (Act) prohibits the referral of patients by a health care provider to an entity that the referring health care provider holds a financial interest, if the financial interest is a type that is regulated by the Act and an exemption does not apply.¹⁸ The prohibition against patient self-referral stems from a concern that a health care practitioner with a personal financial involvement may overutilize health care services, driving up the cost of health care and possibly adversely affecting quality.¹⁹

The Act does not apply to certain financial interests, including an investment interest in an entity which owns or leases and operates a hospital.²⁰ For those financial interests subject to the Act, a health care provider is prohibited from referring a patient to an entity that the health care provider has an investment interest, unless:²¹

- For entities whose shares are publicly traded:
 - 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; and
 - The entities total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million; or
- For entities other than publicly held corporations:
 - 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;

⁸ 42 USC s. 1320a-7b(b).

⁹ Id.

¹⁰ Id.

¹¹ Id.

¹² 42 USC s. 1320a-7a.

¹³ Supra, FN 8.

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ 42 U.S.C. § 1320a-7a(a)(5)

¹⁸ S. 456.053, F.S.

¹⁹ S. 456.053(2), F.S.

²⁰ S. 456.053(3)(k), F.S.

²¹ S. 456.053(5)(b), F.S.

- 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;
- 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; and
- 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.

The entity in which the health care provider holds an interest must also meet the following conditions for a referral to be exempt for the Act:²²

- 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; and
- 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, and invested in the entity or corporation by that investor.

A violation of the Act subjects the provider 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;²³
- Discipline by his or her regulatory board (hospitals are subject to penalties imposed by the Agency for Health Care Administration (AHCA));²⁴ and
- Being charged with a first-degree misdemeanor²⁵ 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., which requires a physician to disclose to a patient if he or she has a financial interest in an entity to which the patient is being referred.²⁶

A health care provider may not submit a claim for payment for a services provided pursuant to a referral prohibited by the Act; and if the provider receives payment for such services, he or she must be refund the payment.²⁷ 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.²⁸

Anti-Kickback Statutes

Individual health care practitioners are prohibited from providing or receiving kickbacks for referring patients. Section 395.0185, F.S., prohibits any person from paying a commission, bonus, kickback,²⁹ 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.³⁰ A health care provider is also specifically prohibited from offering, paying, soliciting or receiving a kickback, directly or indirectly, overtly or covertly, in cash or in kind for referring or soliciting a patient.³¹

²² Id.

²³ S. 456.053(5)(f), F.S.

²⁴ S. 456.053(5)(g), F.S.

²⁵ A first-degree misdemeanor is punishable by up to one year in jail and a \$1,000 fine. Ss. 775.082 and 775.083, F.S.

²⁶ S. 456.053(5)(j), F.S.

²⁷ S. 456.053(5)(c)–(d), F.S.

²⁸ S. 456.053(5)(e), F.S.

²⁹ A kickback is a remuneration or payment, by or behalf of a health care provider to any person as an incentive or inducement to refer patients for past or future services. S. 456.054(1), F.S.

³⁰ The Agency for Health Care Administration (AHCA) enforces this provision and if the violator is not licensed by AHCA, the law authorizes AHCA to impose a fine of up to \$1,000 nonetheless, and to recommend disciplinary action to the appropriate licensing board.

³¹ S. 456.054, F.S. Violations of this provision are considered patient brokering.

Patient Brokering

Patient brokering is paying to induce, or make a payment in return for, a referral of a patient to or from a health care provider or health care facility. Such payments include commissions, bonuses, rebates, kickbacks, bribes, split-fee arrangements, in cash or in kind, provided directly or indirectly.³² A violation of the patient brokering statute is punishable as either a first³³, second³⁴, or third-degree felony,³⁵ based on the number of patients involved, and may also be remedied by an injunction. A private action under the patient brokering statute may recover reasonable expenses, including attorney fees.³⁶

Effect of the Bill

HB 601 amends s. 456.053, F.S., regulating financial arrangements between referring health care providers and health care service providers, to alter a safe harbor provision for permitted referrals from a health care provider to another provider for DHS that solely serves patients of the referring health care provider. Under current law, such referrals, for purposes of the safe harbor protection from state self-referral and kickback prohibitions in state law, require that the DHS be provided under direct supervision of a physician who is present in the office suite where the services are provided. The bill removes the direct supervision requirement and the requirement that the physician be present in the office suite, allowing general supervision of such services from locations outside of the office where the services are provided.

The bill allows self-referring health care providers to avoid the cost of having a physician present while health care services are provided. The change in state law also aligns with federal Stark law provisions regarding self-referrals by a health care provider to another provider in which the referring physician has a financial or other pecuniary interest.

The bill provides an effective date of July 1, 2023.

B. SECTION DIRECTORY:

Section 1: Amending s. 456.053, F.S., relating to financial arrangements between referring health care providers and providers of health care services.

Section 2: Amending s. 641.316, F.S., relating to fiscal intermediary services.

Section 3: Providing an effective date of July 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

³² S. 817.505(1), F.S.

³³ A violation involving 20 or more patients is a first-degree felony and a mandatory \$500,000 fine. S. 817.505(4)(c), F.S. A first-degree felony is punishable by up to 30 years imprisonment. S. 775.082, F.S.

³⁴ A violation involving between 10-19 patients is a second-degree felony and a mandatory \$100,000 fine. S. 817.505(4)(b), F.S. A second-degree felony is punishable by up to 15 years imprisonment. S. 775.082, F.S.

³⁵ A violation involving fewer than 10 patients is a third-degree felony and a mandatory \$50,000 fine. S. 817.505(4)(a), F.S. A third-degree felony is punishable by up to five years imprisonment. S. 775.082, F.S.

³⁶ Ss. 817.505(4), (6), F.S.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Physicians and physician groups who own other medical service providers to which they refer their own patients will forego the cost of having a physician present at all times that designated health services are provided.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES