

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 Appropriations Committee on Health and Human Services

BILL: SB 768

INTRODUCER: Senator Martin

SUBJECT: Referral of Patients by Health Care Providers

DATE: April 11, 2023

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Stovall</u>	<u>Brown</u>	<u>HP</u>	Favorable
2.	<u>McKnight</u>	<u>Money</u>	<u>AHS</u>	Pre-meeting
3.	_____	_____	<u>FP</u>	_____

I. Summary:

SB 768 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 designated health services 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 revenues or state expenditures.

The bill takes effect on July 1, 2023.

II. Present Situation:

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.¹ The purpose of the Act is to prevent conflicts of interest relating to patient referrals by health care

¹ Section 456.053, F.S

providers to a provider of certain health care services in which the referring provider has an investment or other financial interest. The Legislature recognized 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. This section of statute also provides guidance to health care providers regarding prohibited, and authorized, patient referrals under Florida law.

Specifically, the Act prohibits a health care provider from referring a patient for the provision of designated health services (DHS) or any other health care items or service to an entity in which the health care provider is an investor or has an investment interest.² DHS include:³

- Clinical laboratory services,
- Physical therapy services,
- Comprehensive rehabilitative services (speech, occupational, or physical therapy services provided on an outpatient or ambulatory basis),⁴
- Diagnostic-imaging services (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)⁵, and
- Radiation therapy services.

For purposes of the Act:

- A health care provider is a medical doctor, osteopathic physician, chiropractor, podiatrist, advanced practice registered nurse (APRN) who is registered to practice autonomously, optometrist, or dentist.⁶
- A group practice is a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association:
 - In which substantially the full range of services provided by each member, including medical care, consultation, diagnosis, or treatment, are provided through the joint use of shared office space, facilities, equipment, and personnel;
 - For which substantially all of the services provided by the group members 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
 - 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.⁷
- A sole provider is one health care provider who maintains a separate medical office and a medical practice separate from any other health care provider and who bills for his or her services separately from the services provided by any other health care provider. A sole

² Section 456.053(5)(a) and (b), F.S.

³ See s. 456.053(3)(c), F.S.

⁴ See s. 456.053(3)(b), F.S.

⁵ See s. 456.053(5)(d), F.S.

⁶ Section 456.053(3)(i), F.S., referring to a physician licensed under ch. 458, F.S., (medicine), ch. 459, F.S. (osteopathic medicine), ch. 460, F.S., (chiropractic medicine), or ch. 461, F.S. (podiatric medicine); an advanced practice registered nurse (APRN) registered for autonomous practice under s. 464.0123, F.S.; or any health care provider licensed under ch. 463, F.S., (optometry), or ch. 466, F.S., (dentistry).

⁷ Section 456.053(3)(h), F.S.

provider may not share overhead expenses or professional income with any other person or group practice.⁸

- A patient of a group practice or patient of a sole provider is 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.⁹

Numerous exceptions exist to the provisions prohibiting self-referral, either in the form of what constitutes an investment interest,^{10, 11} such as a limited investment in a publicly held corporation or exceptions to the definition of a referral. Within this statutory definition of a referral, there are 13 orders, recommendations, or plans of care by specified health care providers that do not constitute a referral by a health care provider and therefore are not prohibited self-referrals.¹²

The focus of the bill is on one of those exceptions, in s. 456.053(3)(p)3.f., F.S. This exception allows a sole provider or member of a group practice to prescribe or order DHS or other health care items or services for his or her own patients which are to be provided by the sole provider's practice or group practice and the services must be provided or performed under the direct supervision of the referring health care provider or group practice. The exception continues with the following: provided, however, a medical doctor, osteopathic physician, chiropractor, podiatrist, or autonomous APRN 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 bills both the technical and the professional fee for or on behalf of the patient, if the referring physician or autonomous APRN has no investment interest in the practice. Additional parameters for these diagnostic imaging services are provided in the statute.¹³

Under the Act, "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. "Present in the office suite" is defined to mean 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.

Florida's level of supervision, direct supervision, applies to all DHS or other health care items or services for authorized referrals and is stricter than many of the state practice acts and the federal Stark Law.

The submission of claims for payment of services provided through a prohibited referral, without a timely refund of any collection, subjects the health care provider to a civil penalty of up to \$15,000 for each billing and collection, or up to \$100,000 for each billing and collection if cross-

⁸ Section 456.053(3)(r), F.S.

⁹ Section 456.053(3)(n), F.S.

¹⁰ Section 456.053(5)(b), F.S.

¹¹ Section 456.053(3)(k), F.S.

¹² See s. 456.053(3)(p), F.S.

¹³ See s. 456.053(3)(p)3.f., F.S.

referrals or similar schemes are involved.¹⁴ The health care provider is also subject to disciplinary action by the applicable state practitioner regulatory board.

The 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 DHS payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship (ownership, investment, compensation arrangement), unless an exception applies.¹⁵ . The following items or services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- 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.
- Inpatient and outpatient hospital services.¹⁶

The federal regulations implementing the Stark law were recently updated to coordinate the care among physicians and other health care providers to improve the care of the patients they serve.¹⁷ This rule provides exceptions to the referral prohibitions for, among other things, physician services and in-office ancillary services if the services are furnished personally; by another physician in the referring physician’s group practice; or by another individual who is supervised by the referring physician or another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.¹⁸

¹⁴ Section 456.053(5)(c),(d),(e), and (f), F.S.

¹⁵ 42 U.S.C. s. 1395nn, (1989)

¹⁶ See Centers for Medicare & Medicaid Services, *Physician Self-Referral*, available at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index?redirect=/physicianselfreferral/> (last visited Mar. 15, 2022).

¹⁷ See Centers for Medicare & Medicaid Services, *Newsroom Fact Sheet Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (CMS-1720-F)* dated November 20, 2020, available at <https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f> (last visited Mar. 15, 2023).

¹⁸ See 85 Federal Register 77492, 77667; 42 C.F.R. s. 411.355, published December 2, 2020, effective January 19, 2021, available at <https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf> (last visited Mar. 13, 2023).

Several documents address the payment and coverage rules such as the Medicare Benefit Policy Manual,¹⁹ the Medicare Claims Processing Manual,²⁰ and the Code of Federal Regulations (CFR). These documents set forth, among other things, the level of supervision required as a condition of coverage for different health care services paid for by Medicare. For example, with respect to diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests 42 CFR s. 410.32(b)(3), requires:

Except where otherwise indicated, all diagnostic X-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision ... In addition, some of these tests also require either direct or personal supervision.²¹

As an example of an exception to the general level of supervision, 42 CFR s. 410.32(b)(4), requires:

For diagnostic tests that are performed by a registered radiologist assistant who is certified and registered by the American Registry of Radiologic Technologists ... and that would otherwise require a personal level of supervision ... may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

The Centers for Medicare & Medicaid Services (CMS) establishes the required level of supervision based on the type of service performed, the setting where the service is performed and the physical location of where the service is performed. There are three levels of supervision:²²

- General supervision, which means the procedure is furnished under the supervising physician's overall direction and control but the physician's physical presence is not required during the procedure's performance.
- Direct supervision, which means the supervising physician must be present and immediately available to furnish assistance and direction throughout the procedure's performance. It does not mean the physician must be physically present in the room when the procedure is performed.²³
- Personal supervision, which means the physician must be physically present in the room during the procedure's performance.

III. Effect of Proposed Changes:

The bill 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

¹⁹ See Section 80, chapter 15, of Pub. 100-02, Medicare Benefit Policy, which sets forth the various levels of physician supervision required for diagnostic tests, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf> (last visited Mar. 15, 2023).

²⁰ See Chapter 13, Medicare Claims Processing Manual – Radiology Services and other Diagnostic Procedures, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/clm104c13.pdf> (last visited Mar. 15, 2023).

²¹ See 42 CFR s. 410.32(b); (10/1/21 edition), available at <https://www.govinfo.gov/content/pkg/CFR-2021-title42-vol2/pdf/CFR-2021-title42-vol2-part410.pdf> (last visited Mar. 15, 2023).

²² *Id.*

²³ Until the end of the calendar year in which the COVID-19 Public Health Emergency ends (which will be the end of 2023), the presence of the physician includes virtual presence through audio/video real-time communications technology (excluding audio-only).

referrals from a health care provider to another provider for designated health services (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 also includes conforming statutory cross-references.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Relaxing the level of supervision so that the referring physician or a physician in the group practice is not required to be physically present when certain services are performed, may allow for a more efficient and cost-effective use of physician health care resources.

C. Government Sector Impact:

The bill does not appear to have a fiscal impact on state revenues or state expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.053 and 641.316.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.