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: SB 768

INTRODUCER: Senator Martin

SUBJECT: Referral of Patients by Health Care Providers

DATE: March 17, 2023 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Pre-meeting**
2.			AHS	
3.			FP	

I. Summary:

SB 768 removes the requirement for a referring health care provider or group practice to engage in direct supervision when a designated health service or other health care item or service is furnished within the parameters of service delivery that is excluded from the prohibition on self-referrals found in s. 456.053, F.S. Instead, to satisfy the exception, the supervision level must comply with all applicable Medicare payment and coverage rules for services.

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

II. Present Situation:

Section 456.053, F.S., contains the “Patient Self-Referral Act of 1992” (Act). The purpose of the Act is to prevent conflicts of interest relating to patient referrals by health care 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 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.[1] Designated health services (DHS) are:[2]

- Clinical laboratory services,
- Physical therapy services,

[1] Section 456.053(5)(a) and (b), F.S.

[2] *See* s. 456.053(3)(c), F.S.

- Comprehensive rehabilitative services (speech, occupational, or physical therapy services provided on an outpatient or ambulatory basis),[3]
- 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)[4], 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.[5]
- 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.[6]
- 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 provider may not share overhead expenses or professional income with any other person or group practice.[7]
- 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.[8]

Numerous exceptions exist to the provisions prohibiting self-referral, either in the form of what constitutes an investment interest,[9, 10] 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

[3] *See* s. 456.053(3)(b), F.S.
[4] *See* s. 456.053(5)(d), F.S.
[5] Section 456.053(3)(i), F.S., referring to a physician licensed under ch. 458, F.S., (medicine), ch. 459, F.S. (osteopthic 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).
[6] Section 456.053(3)(h), F.S.
[7] Section 456.053(3)(r), F.S.
[8] Section 456.053(3)(n), F.S.
[9] Section 456.053(5)(b), F.S.
[10] Section 456.053(3)(k), F.S.

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.[11]

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

[11] Section 456.053(3)(p), F.S. "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, a physician licensed pursuant to chapter 458, chapter 459, chapter 460, or chapter 461 or an advanced practice registered nurse registered under s. 464.0123 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 or advanced practice registered nurse registered under s. 464.0123 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 than 15 percent of their patients receiving diagnostic imaging services from outside referrals, excluding radiation therapy services. However, the 15 percent limitation of this sub-subparagraph and the requirements of subparagraph (4)(a)2. do not apply to a group practice entity that owns an accountable care organization or an entity operating under an advanced alternative payment model according to federal regulations if such entity provides diagnostic imaging services and has more than 30,000 patients enrolled per year.
g. By a health care provider for services provided by an ambulatory surgical center licensed under chapter 395.
h. By a urologist for lithotripsy services.
i. 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.
j. By a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice.
k. By a nephrologist for renal dialysis services and supplies, except laboratory services.
l. By a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in such private residences, except for services rendered by a home health agency licensed under chapter 400. For purposes of this sub-subparagraph, the term "private residences" includes patients' private homes, independent living centers, and assisted living facilities, but does not include skilled nursing facilities.
m. By a health care provider for sleep-related testing.

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.[12]

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 designated health services or other health care items or services for authorized referrals and is stricter that many of the state practice acts and the federal Stark Law, which is described below.

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-referrals or similar schemes are involved.[13] The health care provider is also subject to disciplinary action by the applicable state practitioner regulatory board.

The Federal Stark Law

A similar law exists at the federal level, commonly referred to as the Stark Law.[14] The Stark Law prohibits a physician from making referrals for certain designated health services (DHS) to an entity with which the physician, or an immediate family member, has a financial relationship (ownership, investment, compensation arrangement) and billing Medicare (or other payers), unless an exception applies. 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.

[12] *See* s. 456.053(3)(p)3.f., F.S.
[13] Section 456.053(5)(c),(d),(e), and (f), F.S.
[14] 42 U.S.C. s. 1395nn, (1989)

- Inpatient and outpatient hospital services.[15]

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.[16] 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.[17]

Several documents address the payment and coverage rules such as the Medicare Benefit Policy Manual,[18] the Medicare Claims Processing Manual,[19] 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.[20]

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

---

[15] *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 March 15, 2022).

[16] *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 March 15, 2023).

[17] *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 March 13, 2023.

[18] *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 March 15, 2023).

[19] *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 March 15, 2023).

[20] *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 March 15, 2023).

and the physical location of where the service is performed. There are three levels of supervision:[21]

- 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.[22]
- Personal supervision, which means the physician must be physically present in the room during the procedure's performance.

III. Effect of Proposed Changes:

SB 768 conforms the level of supervision required in the prohibited referral exception related to referrals within a sole provider's practice or group practice to the standard and terminology used in the regulations of the federal Stark Law.

Specifically, the bill removes the requirement for the referring health care provider or group practice to engage in direct supervision when the service is furnished and instead requires the supervision to comply with all applicable Medicare payment and coverage rules for services. The Medicare payment and coverage rules for services include a reference to compliance with state law and state scope of practice regulations which will help ensure patient safety if Florida's supervision requirements exceed those in the Medicare payment and coverage rules.

The bill removes the definitions of "direct supervision" and "present in the office suite" which become unnecessary with the removal of the requirement for direct supervision.

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.

---

[21] *Id.*

[22] 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).

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:

None.

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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.