

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 425 Physician Fee Sharing Task Force
SPONSOR(S): Health & Human Services Committee; Health Quality Subcommittee; Plasencia and others
TIED BILLS: IDEN./SIM. **BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N, As CS	Siples	McElroy
2) Commerce Committee	24 Y, 1 N	Peterson	Hamon
3) Health & Human Services Committee	15 Y, 0 N, As CS	Siples	Calamas

SUMMARY ANALYSIS

The federal Ethics in Patient Referrals Act of 1989, commonly known as the Stark Law, 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.

Similarly, the Florida Patient Self-Referral Act of 1992 prohibits a Florida health care provider from referring a patient for a designated health service to an entity in which the health care provider has an investment interest, regardless of payor. Designated health services include clinical laboratory services, physical therapy services, comprehensive rehabilitation services, diagnostic imaging services, and radiation services. A health care provider is also prohibited from referring a patient for any other health care item or service that the provider has an investment interest in, with limited exceptions.

Florida and federal law also prohibits a health care provider 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. Violations of the prohibition of the Florida law are considered patient brokering.

CS/CS/HB 425 creates a task force within the Department of Health (DOH) to address the issues related to barriers to innovation and modernization of provider payment models created by federal and state law, and requires the task force to report its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 2018.

The bill requires the task force members to serve without compensation or reimbursement for per diem and travel expenses. DOH must use existing and available resources to administer and support the activities of the task force.

The bill has an insignificant negative fiscal impact on DOH, which must be absorbed within existing resources. The bill has no fiscal impact on local governments.

The bill is effective upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

The Stark Law

The federal Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law,¹ 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.² Under the Stark law, designated health services include:³

- Clinical laboratory services;
- Physical therapy;
- Occupational therapy;
- Outpatient speech-language pathology services;
- Radiology services, including magnetic resonance imaging (MRI), computerized axial tomography scans, and ultrasound 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.

The Stark Law is a strict liability statute, which means no specific intent to violate the law is needed.⁴ The Stark Law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals.⁵ Physicians who violate the Stark Law may be assessed fines and/or monetary penalties, subject to repayment, or be excluded from participation in the federal health care programs.⁶ A violation of the Stark Law may also result in liability under the False Claims Act, also referred to as the Lincoln Law. The False Claims Act imposes civil liability on individuals who knowingly defraud federal governmental programs.⁷

The Stark Law includes a number of exceptions to the prohibition on self-referral for the designated health services, including:⁸

- Physician services personally provided by or provided under the personal supervision of another physician who is a member of the referring physician's group practice;
- Certain in-office ancillary services that are personally furnished by or provided under the supervision of the referring physician or another physician who is a member of the referring physician's group practice;

¹ 42 U.S.C. s. 1395nn.

² Centers for Medicare & Medicaid Services, *Physician Self Referral*, (Jan. 5, 2015), available at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html> (last visited January 27, 2018).

³ *Supra* note 1.

⁴ Department of Health and Human Services, Office of Inspector General, *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*, available at https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf (last visited January 27, 2018).

⁵ *Id.*

⁶ *Id.*

⁷ See 31 U.S.C. ss. 3729-3733.

⁸ 42 C.F.R. s. 411.355. Specific conditions for exclusion may apply.

- Services furnished by an organization to its enrollees, such as certain health management organizations or health care prepayment plan;
- Services provided by an academic medical center if the referring physician is a bona fide employee, has a bona fide faculty appointment at the affiliated medical school, and provides substantial academic services or clinical teaching;
- Certain implants furnished at an ASC, such as cochlear implants, intraocular lenses, and other implanted prosthetic devices or durable medical equipment;
- Erythropoietin or other dialysis-related drugs that meet certain conditions;
- Preventive screening tests, immunizations, and vaccines;
- Eyeglasses and contact lenses following cataract surgery; and
- Intra-family rural referrals if the referring physician or family member makes reasonable inquiries as to the availability of other persons or entities to furnish the designated health service.

The Stark Law also contains a number of exceptions to the referral prohibition related to other compensation arrangements including, but not limited to:⁹

- 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 is consistent with the fair-market value of the services, does not take into account (directly or indirectly) the volume or value of referrals by the referring physician, and is commercially reasonable even if no referrals were made to the employer;
- 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;
- 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;
- Physician recruitment arrangements paid by a hospital to induce a physician to relocate his or her practice to the geographic area served by the hospital in order to become a part of the hospital's medical staff, provided that the arrangement is not conditioned on the physician's referral of patients to the hospital, and the amount of remuneration does not take into account the volume or value of referrals;
- Certain isolated transactions, such as a one-time sale of property or a practice as long as the amount of remuneration is consistent with fair-market value and does not take into account the volume or value of any referrals by the referring physician;
- Certain arrangements with hospitals;
- Certain group practice arrangements made with hospitals;
- Payments made by a physician for laboratory services or other items or services if paid at fair-market value;
- Bona fide charitable donations by a physician;
- Nonmonetary compensation;
- Fair-market value compensation that is set in advance and not determined in a manner that takes into account the volume or value of any referrals by the referring physician;
- Incidental benefits for medical staff;
- Risk-sharing agreements between a physician and a managed care or independent practice association, as long as it does not violate the anti-kickback statute;
- Certain obstetrical malpractice insurance subsidies;
- Investments in group practices;
- ASCs as long as the remuneration does not include any payment that is a return on investment interest; additional restrictions apply for an ASC for which all the investors are surgeons or physicians, or is partly owned by a hospital;

⁹ 42 C.F.R. s. 411.357.
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- Price reductions offered to eligible managed care organizations;
- Electronic prescribing items and services;
- Electronic health records items and services;
- Medicare Coverage Gap Discount Program; and
- Local transportation.

Florida Patient Self-Referral Act of 1992

Similar to the Stark Law, the Patient Self-Referral Act of 1992 (Act) prohibits the referral of patients by a health care provider for specified services or treatments when the referring health care provider has a financial interest in the service or treatment to be provided.¹⁰ 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, thus driving up the cost of health care and possibly adversely affecting quality.¹¹ Unlike the Stark Law, which only applies to services that are federally funded, the Act applies to all health care services provided in Florida, regardless of payer.

The Act prohibits a health care provider¹² from referring a patient for a designated health service to an entity in which the health care provider has an investment interest.¹³ Designated health services include clinical laboratory services, physical therapy services, comprehensive rehabilitation services, diagnostic imaging services, and radiation services.¹⁴ Additionally, a health care provider is prohibited from referring a patient for any other health care item or service in which the health care provider has an investment interest, unless:

- **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;
 - 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.

Regardless of the type of entity in which the health care provider holds an interest, the entity must also meet the following conditions for a referral to be exempt for the Act:

- 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.

¹⁰ Section 456.053, F.S.

¹¹ Section 456.053(2), F.S.

¹² Section 456.053(3)(i), F.S., defines "health care provider" as a Florida-licensed allopathic physician, osteopathic physician, chiropractic physician, podiatric physician, or any health care provider licensed in an optometric or dentistry profession.

¹³ Section 456.053(5)(a), F.S.

¹⁴ Section 456.053(3)(c), F.S.

The Act provides exceptions to the prohibited referrals, which include any order, recommendation, or plan of care by a:¹⁵

- Radiologist for diagnostic-imaging services;
- Physician specializing in the provision of radiation therapy services for such services;
- 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 with treating such a patient for cancer and related complications;
- Cardiologist for cardiac catheterization services;
- 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;
- 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;
- Health care provider for services provided by a licensed ambulatory surgical center (ASC);
- Urologist for lithotripsy services;
- 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;
- Physician for infusion therapy services to a patient of that physician or a member of that physician's group practice;
- Nephrologist for renal dialysis services and supplies;
- 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 licensed home health agency; or
- Health care provider for sleep-related testing.

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.¹⁶

A health care provider found to have violated the Act is 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;¹⁷
- Discipline by his or her regulatory board (hospitals are subject to penalties imposed by the Agency for Health Care Administration (AHCA));¹⁸ and
- 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., 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.¹⁹

¹⁵ Section 456.053(3)(o), F.S.

¹⁶ Sections 456.053(5)(j) and 456.052, F.S.

¹⁷ Section 456.053(5)(f), F.S.

¹⁸ Section 456.053(5)(g), F.S.

¹⁹ Section 456.053(5)(j), F.S.

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.²⁰ 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.²¹

The Florida law is more restrictive than the Stark Law because it allows fewer exceptions to its provisions and applies to all health care services regardless of payer. Although the Act is more restrictive, it does not frustrate the intent of the Stark Law.²²

Anti-Kickback and Patient Brokering Prohibitions

Federal and State Anti-Kickback Statutes

Federal law prohibits payment 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.²³ Violation of the federal anti-kickback statute is a felony that is punishable by a fine of up to \$25,000 or up to 5 years in prison, or both.²⁴ 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.

In Florida, both facilities and individual health care practitioners are prohibited from providing or receiving kickbacks for the referral of patients. Section 395.0185, F.S., prohibits any person from paying a commission, bonus, kickback,²⁵ 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.²⁶ 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.²⁷

Patient Brokering

Florida's patient brokering statute, s. 817.505, F.S., makes it unlawful for any person to engage in 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.²⁸ A violation of the patient brokering statute is a third degree felony,²⁹ and may also be

²⁰ Section 456.053(5)(c)-(d), F.S.

²¹ Section 456.053(5)(e), F.S.

²² *Fresenius Medical Care Holdings, Inc. v. Tucker*, 704 F.3d 935 (11th Cir. 2013).

²³ 42 U.S.C. s. 1320a-7b(b).

²⁴ Id.

²⁵ 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.)

²⁶ 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.

²⁷ Section 456.054, F.S. Violations of this provision are considered patient brokering.

²⁸ Section 817.505(1), F.S.

²⁹ A third degree felony is punishable by not more than five years of imprisonment and not more than a \$5,000 fine. (ss. 775.082, 775.083, F.S.)

remedied by an injunction or any other enforcement process. Private entities bringing an action under the patient brokering statute may recover reasonable expenses, including attorney fees.³⁰

The patient brokering statute has been used in cases involving split-fee arrangements. For example, it was used in an assignment of benefits case in which a non-provider suggested a patient go to a particular MRI facility, paid the facility for the MRI and billed the insurer a greater amount.³¹ It has also been used in self-referral arrangements. For example, it was used in a case where an arrangement by which a series of shell companies, nominal owners, and independent contractors were used to conceal relationships that generated a high volume of personal injury protection patients to a particular provider through a toll-free referral number.³²

Fee-Splitting by Physicians

A physician is subject to licensure disciplinary action if the physician pays or receives a commission, bonus, kickback, or rebate, or engages in a split-fee arrangement in any form with a physician, organization, agency, or person, either directly or indirectly, for patients referred to health care providers, including but not limited to:³³

- Hospitals;
- Nursing homes;
- Clinical laboratories;
- ASCs; or
- Pharmacies.

In *Crow v. Agency for Health Care Administration*, the court upheld the Board of Medicine's interpretation of the statute that would permit a salary arrangement that is based on the fees generated for the professional services provided by the physician, as well as those services provided under the physician's direct supervision (such as an advanced registered nurse practitioner or physician assistant).³⁴

Effect of Proposed Changes

CS/CS/HB 425 creates the Physician Fee Sharing Task force within DOH to develop and evaluate policy proposals to identify and address barriers created by the Stark Law, the Florida Patient Self-Referral Act of 1992, federal and state anti-kickback laws, and the state patient brokering law to innovation and modernization of provider payment models. The task force must develop and evaluate policy proposals related to:

- Implementing and maintaining alternative payment models;
- Increasing or extending existing safe harbor provisions to include physician practice groups; and
- Reforming the liability standard for violations.

The task is comprised, at a minimum, of the following 26 members:

- The State Surgeon General or his or her designee, who serves as the chair of the task force;
- The Secretary of AHCA or his or her designee;
- The Attorney General or his or her designee;

³⁰ Section 817.505(4), (6), F.S.

³¹ *Medical Management Group of Orlando, Inc. v. State Farm Mut. Auto. Ins. Co.*, 811 So. 2d 705 (Fla. 5th DCA 2002).

³² *State Farm Mut. Auto. Ins. Co. v. Physicians Group of Sarasota, L.L.C.*, 9 F. Supp. 3d 1303 (M.D. Fla. Mar. 25, 2014) (denying motion to dismiss).

³³ Sections 458.331(1)(i) and 459.015(1)(j), F.S. However, this does not prevent a physician from receiving a fee for professional consultation services.

³⁴ 669 So.2d 1160 (Fla. 5th DCA 1996).

- Two members of the Legislature appointed by the Governor;
- Two members of the Senate appointed by the President of the Senate;
- Two members of the House of Representatives appointed by the Speaker of the House of Representatives;
- Two representatives of hospitals or facilities licensed under chapter 395, who each regularly deal with health care fraud and abuse matters, particularly those relating to the federal False Claims Act, federal Ethics in Patient Referrals Act of 1989, and anti-kickback issues, appointed by the Secretary of AHCA;
- A general counsel of a health insurer or his or her designee, who is familiar with health care fraud and abuse matters, particularly those relating to the federal False Claims Act, federal Ethics in Patient Referrals Act of 1989, and anti-kickback issues, appointed by the Secretary of AHCA;
- Five health care practitioners, each of whom practices in a different area of medicine, appointed by the State Surgeon General;
- A representative of an organization that represents health care practitioners and who is familiar with health care fraud and abuse matters, particularly those relating to the federal False Claims Act, federal Ethics in Patient Referrals Act of 1989, and anti-kickback issues, appointed by the President of the Senate.
- A representative of the Florida Bar, whose practice area primarily involves health care fraud and abuse matters, particularly those relating to the federal False Claims Act, federal Ethics in Patient Referrals Act of 1989, and anti-kickback issues, appointed by the Executive Director of the Florida Bar;
- Two representatives from companies whose primary business function is the development and deployment of a certified electronic health record, appointed by the Speaker of the House of Representatives;
- Two representatives from companies whose primary business function is the development and deployment of health information technology, such as population health or data analytics, which is not a certified electronic health record, appointed by the President of the Senate;
- Two representatives from a company whose primary business function is the development and deployment of smart medical devices, such as remote patient monitoring, appointed by the Speaker of the House of Representatives; and
- A representative from an investment company whose investment portfolio is comprised of at least 20 percent health information technology investments, appointed by the President of the Senate.

The bill requires the task force to conduct its first meeting by June 1, 2018, and to meet as often as needed to fulfill its responsibilities. The task force may meet in person, by teleconference, or by other electronic means. The task force must submit a report of its findings, conclusions, and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 2018.

The bill requires task force members to serve without compensation and prohibits reimbursement for per diem or travel expenses. The bill requires DOH to use existing and available resources to administer and support the activities of the task force.

The section of law created by the bill expires January 1, 2019.

The bill is effective upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0541, F.S, relating to physician fee sharing task force.

Section 2: Provides the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur an insignificant negative fiscal impact; however, the bill requires DOH to use existing and available resources to administer and support the activities of the task force.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 29, 2018, the Health Quality Subcommittee adopted a strike-all amendment and reported HB 425 favorably as a committee substitute. The strike-all amendment:

- Eliminated authorization for physicians to participate in fee sharing;
- Created the Physician Fee Sharing Task Force to address barriers to innovation and modernization of health care provider payment models.

On February 21, 2018, the Health and Human Services Committee adopted an amendment and reported CS/HB 425 favorably as a committee substitute. The amendment added the Florida Patient Self-Referral Act of 1992, the state and federal anti-kickback laws, and the state patient brokering law to the list of laws that the Physician Fee Sharing Task Force is to consider when evaluating and developing policy proposals to address barriers to innovation and modernization of health care provider payment models.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.