

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 726
SPONSOR: Health, Aging and Long-Term Care Committee, Senator Latvala and others
SUBJECT: Financial Arrangements/Referring Providers and Providers of Health Care Services
DATE: January 24, 2002 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable/CS
2.			AHS	
3.			AP	
4.				
5.				
6.				

I. Summary:

This bill removes referrals for diagnostic clinical laboratory services related to renal dialysis from the list of orders, recommendations, or plans of care that are excluded from the definition of *referral* for purposes of the prohibitions contained in the “Patient Self-Referral Act of 1992.” Thus, a health care provider would be prohibited from referring patients for diagnostic laboratory services related to renal dialysis to a clinical laboratory in which the referring provider had a financial interest.

The bill adds an exclusion from the definition of *referral* for a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in the private residence.

This bill amends s. 456.053, F.S.

II. Present Situation:

End Stage Renal Disease/Kidney Dialysis

Kidney dialysis is an artificial means of filtering waste products from the blood when the kidneys have failed to do so. In kidney disease, often referred to as End Stage Renal Disease (ESRD), dialysis is a life-saving treatment. Patients most commonly receive dialysis three times per week in sessions that last several hours. Dialysis is not a cure for ESRD, but rather is a way of keeping a patient alive until he or she can receive a kidney transplant. Laboratory testing of the patient’s blood is an essential component of dialysis services, providing a physician information about the patient’s renal condition.

There are primarily four major companies providing ESRD services in Florida: DaVita, Inc., also known as Total Renal Laboratories, with a laboratory located in Deland; ESRD Laboratories, with a laboratory located in Broward County; Fresenius, a German company with U.S. headquarters in Lexington, Massachusetts; and Gambro Healthcare, Inc., a Swedish company with laboratory headquarters located in Broward County.

In 1972, Congress established the Medicare End Stage Renal Disease Program to provide for the medical needs of individuals with ESRD. Most individuals who require dialysis or kidney transplantation to sustain life receive services, including laboratory services, that are paid for by Medicare. Approximately 75-80 percent of ESRD patients in Florida are covered by Medicare which pays a composite rate for dialysis and routine laboratory tests. If additional tests are medically necessary, with proper documentation, they may be paid by Medicare as well. In Florida approximately 500 ESRD patients who do not qualify for Medicare, for lack of work history or other reasons, receive services through Medicaid. ESRD services--both dialysis and routine laboratory services--are paid by an all-inclusive fee under Medicaid. Additional laboratory services would only be covered if provided by an independent laboratory.

Prohibitions on Patient Self-Referral

Section 456.053, F.S., is the Patient Self-Referral Act of 1992" (Patient Self-Referral Act or Act). The 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. The prohibition against patient self-referral originated from an economic concern: a physician with a personal financial involvement in a diagnostic facility or clinical laboratory might prescribe more tests, or more costly tests, than he or she might prescribe without the personal financial incentive, thus driving up the cost of health care.

The Act provides definitions for purposes of its requirements relating to financial arrangements between referring health care providers and providers of health care services. The Act defines *designated health services* to mean clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services. *Referral* is defined to mean any referral of a patient by a health care provider for health care services which includes: the forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies a designated health service or any other health care item or service; or the request or establishment of a plan of care by a health care provider, which includes the provision of a designated health service or other health care item or service. *Health care provider* means any physician licensed under chapter 458, 459, 560, or 461, F.S., or any health care provider licensed under chapter 463 or 466, F.S. Allopathic, osteopathic, chiropractic, and podiatric physicians, optometrists and dentists are health care providers under the Act.

The Patient Self-Referral Act provides exceptions to the prohibited referrals, which include any order, recommendation, or plan of care by:

- a radiologist for diagnostic-imaging services;
- a physician specializing in the provision of radiation therapy services for such services;

- 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 with treating such a patient for cancer and related complications;
- a cardiologist for cardiac catheterization services;
- 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;
- a 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;
- a health care provider for services provided by an ambulatory surgical center licensed under chapter 395, F.S.;
- a health care provider for diagnostic clinical laboratory services where such services are directly related to renal dialysis;
- a urologist for lithotripsy services;
- a 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;
- a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice; and
- a nephrologist for renal dialysis services and supplies.

Florida's Patient Self-Referral Act is similar to a federal prohibition of patient self-referral under 42U.S.C. § 1395nn. The law, popularly known as Stark II, prohibits a physician from referring patients to an entity for the furnishing of designated health services if there is a financial relationship between the referring physician or an immediate family member of the physician and the entity. The federal law provides certain exemptions to the prohibition, including an exemption for clinical laboratory services furnished in an ESRD facility. While Stark II governs services that are federally funded, Florida's Patient Self-Referral Act applies to all health care services provided in Florida.

Studies of Laboratory Services for Dialysis Patients

In 2001, the Agency for Health Care Administration (AHCA or Agency) published a report on *Laboratory Services for Dialysis Patients in Florida* in response to a request by the 1999 Legislature. The Legislature asked the Agency to analyze six areas: past and present utilization rates of clinical lab services for dialysis patients; financial arrangements among dialysis centers and among centers and medical directors; business relationships and affiliations with clinical labs; the extent of self-referral of dialysis patients to clinical labs; quality and responsiveness of clinical lab services for dialysis patients; and the average annual revenue for dialysis patients for clinical lab services in the past 10 years.

The Agency encountered a lack of consistent data that made it impossible to answer several of the questions. The report stated that Florida's dialysis industry is dominated by three large

national health care corporations. Only four centers reported that they were owned by their medical director. The report did not contain information on utilization rates. The report stated, "The issue of lab test utilization could not be ascertained as neither Fresenius nor Gambro, the two major players in the Florida dialysis market, chose to respond to the request for information citing proprietary issues. Without the cooperation of the mentioned companies, the Agency would be required to commit investigative resources that the legislature did not provide in order to secure reliable data." The Agency recommended that the Legislature provide funding for a study by one of the state universities or a private consultant.

The University of South Florida's (USF) College of Public Health produced the *2001 Florida Dialysis Study* which addressed the issues of laboratory test utilization; financial arrangements among dialysis centers, their medical directors, and any business relationships and affiliations with clinical laboratories; any self-referral of dialysis patients to clinical laboratories; and the quality and responsiveness of clinical lab services for dialysis patients. The researcher at USF obtained information and documents that were previously considered proprietary, and the report contains much useful information about the dialysis industry. However, regarding the question of utilization costs, the report states, "Fresenius and Davita have provided summary data, though the two data sets are not compatible. Gambro did not provide data, despite initial assurances that it would." In a conclusion similar to that of the AHCA study, the USF study found that the Legislature's concerns could not be addressed due to the lack of subpoena power on the part of those conducting the study and an absence of standardized reporting requirements for dialysis organizations.

In 2001, the Committee on Health Regulation of the Florida House of Representatives conducted an interim project on ESRD care. Committee staff reviewed the two previous legislatively mandated studies and examined the need for the exemptions granted to clinical laboratories and nephrologists under the Patient Self-Referral Act. The interim project aimed to determine whether Florida is at financial risk due to fraud or abuse in the Medicaid system. The study also addressed the question of whether the three major companies providing services in Florida control the market, thereby eliminating competition and increasing the cost for services. The report concluded that the Medicaid and Medicare programs are regulated by the state and federal governments with remedies to investigate, fine, and prosecute providers for abuses. Regarding the Patient Self-Referral Act, the report recommended no legislative action, stating that removing the exemption for laboratory services related to dialysis would not increase competition or provide opportunities for competition.

III. Effect of Proposed Changes:

This bill amends s. 456.053(3)(o), F.S., to remove referrals for diagnostic clinical laboratory services related to renal dialysis from the list of orders, recommendations, or plans of care that are excluded from the definition of *referral* for purposes of the prohibitions contained in the "Patient Self-Referral Act of 1992." Thus, a health care provider would be prohibited from referring patients for diagnostic laboratory services related to renal dialysis to a clinical laboratory in which the referring provider had a financial interest.

The bill adds language to s. 456.053(3)(o), F.S., that will not allow a referral exclusion for nephrologists ordering laboratory services related to renal dialysis.

The bill adds an exclusion from the definition of *referral* for a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in the private residence.

The bill provides an effective date of July 1, 2002.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

To the extent that health care providers currently refer patients for clinical laboratory services at facilities the referring provider owns, these private health care providers could be affected negatively. Clinical laboratories that are not owned by these providers could receive more business, if such referrals are prohibited.

The newly created exclusion for a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in the private residence would benefit providers of such services.

C. Government Sector Impact:

Medicare is the most prevalent source of funding for laboratory services related to dialysis services. The payment amounts are established by the federal government. If the bill were to have an impact on state expenditures, the amount, and whether it would be a positive or negative impact, is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
