

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

FRESENIUS MEDICAL CARE
HOLDINGS, INC., et al.,

Plaintiffs,

vs.

CASE NO: 4:03cv411-SPM/GRJ

M. RONY FRANCOIS, M.D., M.P.H.S. Ph.D.,
in his official capacity as Secretary of
the Florida Department of Health; et al.,

Defendants.

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

This cause comes before the Court on the parties' cross motions for summary judgment. Docs. 86 and 94. At issue is whether the Florida referral statute, which prohibits Florida doctors from referring patients for lab work to entities in which they hold an ownership interest, is preempted by Federal law, violates the commerce clause, and violates due process and equal protection. For the following reasons, the Court finds that the Florida statute is an appropriate exercise of state authority. Accordingly, summary judgment will be granted in favor of Defendant.

Background

Plaintiffs are foreign corporations providing renal dialysis services in Florida, either directly or through separate subsidiary corporate entities. They are challenging provisions of Section 456.053, Florida Statutes (“the Florida referral statute”), which regulates physician referrals of patients. The provision of the Florida referral statute at issue makes it unlawful for a physician to refer a patient to clinical laboratory services at an entity in which the physician has ownership or owns stock or debt securities. § 456.053(5)(a), Fla. Stat. Although the Florida referral statute previously exempted renal dialysis from the scope of unlawful referrals, in 2002 the statute was amended to take out the exemption. Ch. 02-389, § 14, Laws of Fla. Under the current provisions of the referral statute, a physician may not refer a patient for renal dialysis services at an entity in which the physician has a financial interest.

A physician who violates the Florida referral statute is subject to disciplinary action by the medical board. § 456.053(5)(f), Fla. Stat. The Florida referral statute also provides a civil penalty of up to \$15,000 for each violation if a person who knows, or has reason to know, that a referral is unlawful presents a bill or claim for payment of such service. § 456.053(5)(e), Fla. Stat.

Plaintiffs filed this action for declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 against the state officials responsible for enforcement of the Florida referral statute. In Count One, Plaintiffs contend that the Florida referral

statute is preempted by Section 1877 of the Social Security Act, commonly referred to as the Physicians Self Referral Law or the "Stark" law, codified at 42 U.S.C. §§ 1395nn. In Count Two, Plaintiffs contend that the Florida referral statute violates the commerce clause because it disproportionately affects foreign corporations that provide integrated renal care and excludes other entities, which are domestic corporations that provide both renal dialysis and laboratory services. In Count Three, Plaintiffs contend that the Florida referral statute violates substantive due process and equal protection standards because the statute is arbitrary and capricious and bears no rational relationship to the public health, safety, morals, or general welfare.

Analysis

1. Federal Stark law does not preempt the Florida referral statute

Preemption is a product of the Supremacy Clause of the United States Constitution, Art. VI, cl. 2, which provides that the laws of the United States "shall be the supreme Law of the Land." This means that when state and federal laws are in conflict, federal law will prevail and thus preempt the state law. Fla. State Conference of the NAACP v. Browning, 522 F.3d 1152, 1167 (11th Cir. 2008).

Sometimes, a federal law contains an express statement that it is displacing state law, making the federal law the sole governing standard. Id. This is known as express preemption. Id. Other times, preemption is implied, such as when Congress legislates so pervasively in a field that there is no room

for state law to operate (known as field preemption) or when the state and federal law are in such conflict that their objectives are at odds or when it would be impossible to comply with both (known as conflict preemption). Id.

This case does not involve express preemption as there is no express provision in the federal Stark law that prohibits states from enacting laws and regulations concerning patient referrals. Instead, Plaintiffs argue for implied preemption based on the need for uniform standards for patient referral under the Medicare and Medicaid programs.

The Stark law generally prohibits a physician from referring Medicare and Medicaid patients for designated health services with an entity in which the physician has a nonexempt financial interest. 42 U.S.C. §§ 1395nn(a)(1) and 1396b(s). The Stark law contains an exemption for referral of clinical laboratory services for end-stage renal disease patients. 42 C.F.R. § 411.351. The Florida referral statute does not contain that exemption and would prohibit that referral. According to Plaintiffs, because the Florida referral statute prohibits what the Stark law would allow, the Florida referral statute conflicts with the Stark law and is therefore preempted. In effect, Plaintiffs' position is that the Stark law created a Federal right, immune from state regulation, for physicians to make referrals that are allowed under the Stark law. Nothing in the language of the law, nor the legislative history, nor the regulations, however, show a clear Congressional intent to do so.

When determining whether a state law is impliedly preempted because it stands as an obstacle to the objectives of Congress, a Court should take care not to stretch the supposed objectives of the federal law to give more than Congress intended. Id. at 1168. “[P]reemption analysis does not justify a ‘freewheeling judicial inquiry into whether a state statute is in tension with federal objectives;’ such an endeavor ‘would undercut the principle that it is Congress rather than the courts that preempts state law.’” Chamber of Commerce of the United States of America v. Whiting, No. 90-115, slip opinion at 22, 2011 WL 203965 at *15 (U.S., May 26, 2011).

The best indication of Congressional intent is the wording of the federal law itself. United States v. Fleet, 498 F.3d 1225, 1229 (11th Cir. 2007). Absent express language in the law, legislative history and federal regulations are also informative in preemption analysis. Hughes v. Attorney General of Fla., 377 F.3d 1258, 1261-64 (11th Cir. 2004). With regard to legislative history, “the authoritative source for finding [Congressional] intent lies in the Committee Reports on the bill, which ‘represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.’” Garcia v. United States, 469 U.S. 70, 76 (1984) (interpreting scope of federal criminal statute).

There is no wording in the Stark law itself that evidences Congressional intent to preempt state laws governing patient referrals. Legislative history from

the Committee Reports to the law, however, expressly state Congressional intent “that Federal law not preempt State laws that are more restrictive.” House Conference Report No. 103-213 at p. 1507 (Doc. 93, ex. 3). Moreover, the regulations implementing the Stark law acknowledge that the Stark law “does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws” 42 C.F.R. 411.350(b). The regulations explain that “although a particular arrangement involving a physician’s financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate . . . other laws administered by . . . [any] State agency.” Id.

Taken together, the wording of the law, the legislative history, and the federal regulations implementing the Stark law show that Congress did not intend to displace more restrictive state laws governing physician referrals. As other Courts have recognized, the regulation of medical fees has traditionally been a state concern that has not been preempted by the federal Medicare statute. Mass. Med. Soc’y v. Dukakis, 815 F.2d 790, 791 (1st Cir. 1987); Penn. Med. Soc’y v. Marconis, 942 F.2d 842, 849 (3d Cir. 1991), Med. Soc’y of the State of N.Y. v. Cuomo, 976 F.2d 812, 816 (2nd Cir. 1992). Likewise, the federal Medicaid program has been recognized as “a cooperative state-federal program” where the case for federal preemption is less persuasive and difficult to establish. Pharm. Research and Mfrs. of Am. v. Meadows, 304 F.3d 1197, 1206 (11th Cir.

2002).

Florida is not alone among the states in regulating self-referrals. See Alice G. Gosfield, Medicare and Medicaid Fraud and Abuse, § 3.30 State self-referral laws (2010). Most states have adopted self-referral regulations. Id. Many have requirements that are more restrictive than the Stark law. Id. Congressional intent to preempt the state laws has not been demonstrated. Accordingly, the Court finds that the Stark law does not preempt the Florida referral statute. Defendants' motion for summary judgment will therefore be granted as to this issue.

2. Florida referral statute does not violate the Commerce Clause

The Commerce Clause of the United States Constitution "confer[s] a 'right' to engage in interstate trade free from restrictive state regulation." Dennis v. Higgins, 498 U.S. 448 (1991). The Commerce Clause does not, however, prevent states from regulating matters of legitimate local concern, even though interstate commerce may be affected. Maine v. Taulor, 477 U.S. 131, 138 (1986). "[L]aws that impose the same burden on in-state and out-of state business interest[s] usually do not violate the Commerce Clause." Ga. Manufactured Hous. Ass'n, Inc. v. Spalding County, 148 F.3d 1304, 1308 (11th Cir. 1998). A non-discriminatory law will violate the Commerce Clause only if "the burden imposed on [interstate] commerce is clearly excessive to the putative local benefits." Id. quoting Pike v. Bruce Church, Inc., 397 U.S. 137, 142

(1970).

In this case, the Florida referral statute applies equally to in-state and out-of-state businesses. It places no special burden on the interstate market. See Executive Town and Country Services v. City of Atlanta, 789 F.3d 1523, 1526 (11th Cir. 1986) (“[T]he commerce clause ‘protects the interstate market, not particular firms, from prohibitive or burdensome regulations.’”). The referral statute serves a legitimate local interest to ensure that treatment choices made by physicians are motivated by the health care needs of their patients, not the financial interests of the physicians. The express legislative intent for the statute is to limit potential conflicts of interests, limit overutilization of health care services, encourage competition, reduce costs, and protect the quality of health care. Fla. Stat. § 456.053(2). Although Plaintiffs question the effectiveness of the Florida referral statute in meeting these goals when it comes to referrals for renal dialysis, similar arguments have been made regarding self-referral regulation generally, including the Stark law. See Alice G. Gosfield, Medicare and Medicaid Fraud and Abuse, § 3.1 Introduction— The self-referral problem (2010). These arguments go to “the wisdom of the statute, not to its burden on commerce.” Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 1127 (1978).

Plaintiffs have not demonstrated that the burden upon interstate commerce imposed by the Florida referral statute is clearly excessive in light of the putative local benefit. Accordingly, the Court finds that the Florida referral

statute does not violate the Commerce Clause. Defendants' motion for summary judgment will therefore be granted as to this issue.

3. Florida referral statute does not violate Due Process

Plaintiffs' final challenge to the Florida referral statute rests on Due Process and Equal Protection grounds. Both sides agree that the rational basis test applies. A statute passes the rational basis test if "there is any reasonably conceivable state of facts that could provide a rational basis for it." Locke v. Shore, 634 F.3d 1185, 1196 (11th Cir. 2011) (internal quotations omitted). No evidence or empirical data is required to support a law under this standard; "rational speculation" will suffice. Id. The rational basis test will be met even if the law "seems unwise . . . or if the rationale for it seems tenuous." Id.

The Florida referral statute passes the rational basis test. The Florida legislature had a legitimate concern that financial self-interest would create potential conflicts of interest and adversely impact the cost and quality of healthcare in Florida. The Florida legislature could have reasonably concluded that self-referrals involving renal dialysis presented the same concerns as other referrals.

Courts have recognized that the determination of which classes will be subject to regulatory restriction "inevitably requires that some persons who have an almost equally strong claim to favored treatment be placed on different sides of the line, and the fact [that] the line might have been drawn differently at some

points is a matter for legislative, rather than judicial, consideration.” FCC v. Beach Commc’ns, Inc., 508 U.S. 307, 315 (1993). “[C]ourts are compelled under rational-basis review to accept a legislature’s generalizations even when there is an imperfect fit between means and ends.” Heller v. Doe, 509 U.S. 312, 321 (1993). The narrow tailoring and least restrictive means required under strict scrutiny test is not required under the rational basis test. See Williams v. Pryor, 240 F.3d 944, 947-48 (11th Cir. 2001) (comparing different levels of scrutiny). The rational basis test is the most deferential to the legislative branch and “proscribes only the very outer limits of a legislature’s power.” Id. at 948. A courts exercise a very limited role under the rational basis test. A court “does not invalidate bad or foolish policies, only unconstitutional ones” and in exercising its authority a court “may not sit as a super-legislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither affect fundamental rights nor proceed along suspect lines.” Id. at 952 (internal quotes omitted).

The Court finds that the Florida referral statute has a rational basis to a legitimate state concern in the cost and quality of healthcare in Florida. Accordingly, Defendants’ motion for summary judgment will be granted as to this issue.

Conclusion

Defendants are entitled to judgment as a matter of law. The Stark law

does not preempt the Florida referral statute. The Florida referral statute does not discriminate against interstate commerce and it is rationally related to a legitimate state purpose. Based on the foregoing, it is

ORDERED AND ADJUDGED:

1. Plaintiffs' motion for summary judgment (doc. 86) is denied.
2. Defendants' cross-motion for summary judgment (doc. 94) is granted. The clerk shall enter judgment in favor of Defendants on all claims.
3. The motion for oral argument (doc. 119) is denied.

DONE AND ORDERED this 27th day of May, 2011.

s/ Stephan P. Mickle

Stephan P. Mickle
Chief United States District Judge