IN THE SUPREME COURT OF FLORIDA

STATE OF FLORIDA,	)	
	)	
Plaintiff/Appellant,	)	
	)	
v.	)	**Case No. SC04-613**
	)	**LT No. 3D03-521**
GABRIEL HARDEN, et al.,	)	
	)	
Defendants/Appellees.	)	
	)	

REPLY BRIEF OF APPELLANT STATE OF FLORIDA

On Appeal From the District Court of Appeal
Third District of Florida

CHARLES J. CRIST, JR.
ATTORNEY GENERAL

CHRISTOPHER M. KISE
Solicitor General
Florida Bar No. 0855545

LOUIS F. HUBENER
Chief Deputy Solicitor General
Florida Bar No. 0140084
LYNN C. HEARN
Deputy Solicitor General
Florida Bar No. 0123633
JASON VAIL
Assistant Attorney General
Florida Bar No. 298824

OFFICE OF THE ATTORNEY GENERAL
The Capitol, Suite PL-01
Tallahassee, FL 32399-1050
(850) 414-3681
Counsel for Appellant,
State of Florida

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

UNITED STATES CODE

CODE OF FEDERAL REGULATIONS

FLORIDA STATUTES

OTHER AUTHORITIES

REPLY ARGUMENT

The theory of defendants' case is that Medicaid-provider-employers may pay "commission-based wages" to employees (their drivers) who provide "marketing services" by "advertising" to Medicaid-eligible children their right to free dental care and transporting them to the employer's office. Defendants contend the State's "anti-marketing" theory criminalizes the drivers' solicitation of commercial business, is preempted by the federal Safe Harbor provision, and violates the First Amendment.

None of this holds a drop of water. The prosecution of defendants has nothing to do with any attempt to stifle marketing or advertising. Paying anyone on a per-head basis to bring in patients is a classic kickback, irrespective of whether the person is a bona fide employee, and a violation of section 409.920(2)(3), Florida Statutes, and the federal Anti-Kickback law, 43 U.S.C. § 1320a-7b(b). That has been the State's position from the beginning. R 2:238-242. Further, defendants never proved they had a bona fide employment relationship within the meaning of the Safe Harbor provision, 42 U.S.C. § 1320a-7b(b)(3)(B), the issue raised by their sworn motion but not ruled on by the trial court.

In a bid for sympathy, defendants suggest that the State has not met its responsibility to inform Medicaid-eligible children

of their right to dental care and failed to provide transportation to such children. The inference defendants obviously wish the Court to draw is that they were providing a "covered service"--transportation--that would entitle them to the Safe Harbor protection. However, under federal law transportation is a responsibility of the States, not Medicaid providers or their so-called "employees." See 42 C.F.R. § 441.62 and 42 C.F.R. § 431.53. (App. A and B). Moreover, there is no claim that any employer, any defendant, or any driver was a "transportation services provider enrolled in the Medicaid program." See Rule 59G-4.330, Fla. Admin. Code. (Init. Br. App. D). See also § 409.905(12), Fla. Stat. (limiting patients' choice of transportation provider).

The decisions below must be reversed because: 1) section 409.920(2)(e), Florida Statutes (2000), is not preempted by the federal Anti-Kickback statute and the Safe Harbor provision; 2) defendants did not prove they had a bona fide employment relationship within the meaning of that provision; 3) solicitation and referral of patients is not a covered item or service; 4) defendants were not charged with negligent conduct; and 5) section 409.920(2)(e) does not violate the First Amendment.

I. THE WILLFULLNESS REQUIREMENT AND THE SAFE HARBOR PROVISION OF THE FEDERAL MEDICAID

ANTI-KICKBACK STATUTE DO NOT PREEMPT SECTION 409.920(2)(e), FLORIDA STATUTES.

1. The Federal Medicaid Law Does Not Reflect A Clear and Manifest Intent To Preempt States' Anti-Kickback Laws.

In attempting to justify payments that are undeniably for patient referrals, defendants ignore the fact that the Medicaid program involves billions of state dollars and that the States, far more than the federal government, have traditionally been in the business of combating crime of all kinds, including policing fraud in state-administered programs. "[T]he principle that the Constitution created a Federal Government of limited powers, while reserving a generalized police power to the States, is deeply ingrained in our constitutional history." United States v. Morrison, 529 U.S. 598, 619 n.8 (2000) (original alterations and quotation marks omitted). Thus, preemption analysis for this case begins with the assumption that the historic police powers of the State are not superseded by federal law "unless that was the clear and manifest purpose of Congress." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). See also New York v. F.E.R.C., 535 U.S. 1, 17-18 (2002).

This presumption applies with particular force to joint or coordinate state and federal programs, such as Medicaid, that are pursuing common purposes. Pharmaceutical Research and Mfrs.

of America v. Walsh, 538 U.S. 644, 666 (2003). And because "the States are independent sovereigns in our federal system" with huge amounts of their own money at risk, the presumption "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." Medtronic, 518 U.S. at 485. See also In Re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 187 (D. Mass. 2003) (noting states have traditionally occupied field of medical fee regulation). Applying these principles, the federal district court in Massachusetts held that the Medicare law does not preempt state consumer protection laws and the Medicaid Rebate Statute does not preempt state law fraud claims. Id. at 186-188; In re Pharm. Indus. Average Wholesale Price Litig., 321 F. Supp. 2d 187, 197-199 (D. Mass. 2004).[1]

Defendants have plainly failed to make the requisite demonstration that it was the clear and manifest purpose of Congress to preempt state law. Allowing payment for patient

[1]Moreover, under our federal system, States do not surrender their rights as sovereigns simply because they participate in a federal program. Given the billions of dollars States contribute to Medicaid, basic considerations of federalism would also require that Congress plainly state its intent to deprive the States of their sovereign right to prosecute their own laws on fraud to protect their own purse. Cf. Atascadero State Hospital v. Scanlon, 473 U.S. 234, 247 (1985)(a State does not waive its immunity from suit in federal court by participating in a federally-funded program unless Congress has clearly conditioned state participation on such a waiver).

referrals invites abuse, as HHS itself recognizes.[2] Even if Congress intended the Safe Harbor provision to protect such payments from federal prosecution, which the State does not for a moment concede, it does not follow that Congress intended to restrain the States from prohibiting this abusive practice. Nowhere in the Medicaid law did Congress express a clear and manifest intent to restrict state prosecution of state fraud laws. To the contrary, Congress requires the States to maintain fraud and abuse control units to prosecute violations of "state laws regarding any and all aspects of fraud. . . ." 42 U.S.C. § 1396b(q) (emphasis added). Harden's brief does not even discuss § 1396b(q) except to misstate it, and the amici briefs ignore it entirely.[3]

The HHS OIG has stated unequivocally that its Safe Harbor regulations do not apply to the States and that the federal statute does not preempt state law. See 54 Fed. Reg. 3088 (Jan. 23, 1989) and 56 Fed. Reg. 35952 (July 29, 1991) (App. D, p. 4,

---

[2]Advisory Opinion 00-7, at p. 3, characterizes as an "abusive arrangement" van drivers soliciting and transporting Medicaid patients when the drivers are compensated on a per patient basis. Op. HHS (Nov. 17, 2000), available at <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_7.htm> (App. C, p. 3).

[3]The Harden brief maintains that all state prosecutions must be approved by the Inspector General, citing 42 U.S.C. § 1396b(q)(3)(B). Harden Br. at 38. This argument misreads (q)(3)(B) and overlooks the preceding sentence, (q)(3)(A).

and E, p. 9).[4] Defendants and the amici argue that these statements must be disregarded because HHS has no "expertise" in preemption. But HHS is the administering federal agency, it coordinates the Medicaid program with the States, and its statements on preemption are entitled to the same deference accorded those of the FDA in Hillsborough County, Florida v. Automated Med. Labs., 471 U.S. 707 (1985). That decision held FDA's statement on the question of implicit intent to preempt "dispositive" unless it was "inconsistent with clearly expressed congressional intent . . . or subsequent developments reveal a change in that position." Id. at 714-715. Neither is the case here.

2. The Conduct Charged Was Not Negligent Or Inadvertent.

Relying on Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995), defendants contend that absent a "willful" element there can be "criminal culpability for mere negligence - i.e., conduct that, "while improper, was inadvertent," and that Congress intended to shield such conduct. Harden Br. at 39.[5]

---

[4]The Harden brief states at p. 28 that the HHS "final rules apply to 'the Federal **and State** health care programs anti-kickback statute,'" purporting to quote 56 Fed. Reg. 35952. The State is unable to locate this quotation. HHS made clear that the final rule does not preempt state anti-kickback statutes. (App. E, p. 9).

[5]Section 409.920(1)(d), Florida Statutes (2000), provided that "[k]nowingly" means done by a person who is aware of or

As shown above, Florida law is not preempted. But in any case, defendants do not contend they were charged with negligent conduct. The pertinent counts of the information charged that defendants "did knowingly . . . solicit, offer, pay or receive remuneration" for referring eligible dental patients. R 1:1-6. The admitted facts establish that defendants either gave or received money they knew was payment for a patient referral. Defendants were aware of the nature of their conduct and the intended result. See § 409.920(1)(d), Fla. Stat. (2000). Their conduct was neither negligent nor inadvertent, and that issue was not properly before the trial court.

For the lower courts to hold section 409.920 (2)(e) facially invalid because it might be applied to negligent conduct was clearly inappropriate based on the authorities cited in the State's initial brief, p. 26. The lower courts therefore erred in holding the Florida law preempted in its entirety.

3. The Mens Rea Requirements of State Anti-Kickback Laws Vary Widely.

Only a small number of state laws track the mens rea language of the federal statute. Five statutes use "knowingly and willfully" or "knowingly and intentionally" language. (App.

---

should be aware of the nature of his or her conduct and that his or her conduct is substantially certain to cause the intended result.

F) Nine state statutes have only the "knowingly" requirement and sixteen have no mens rea language at all. Id. A few States use language such as "corruptly," or "purposely," or "intentionally," and fifteen States apparently have no relevant statute. Id. Eighteen States recognize some form of an employee safe harbor while seventeen do not. Id. It cannot be concluded that the States believe it was Congress' clear and manifest intent to preempt their Medicaid fraud laws.

II. IRRESPECTIVE OF WHETHER SECTION 409.920(2)(e) MIGHT BE PREEMPTED, DEFENDANTS HAVE FAILED TO SHOW THE SAFE HARBOR PROVISION APPLIES TO THEM.

The federal Safe Harbor provision shelters payments "by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services. . . ." 42 U.S.C. § 1320a-7b(b)(3)(B). Defendants did not establish that their drivers had a bona fide employment relationship or that they were employed to provide and did provide covered items or services.

1. No Bona Fide Employment Relationship

Defendants do not deny that the trial court never ruled on the sworn motion to dismiss the information but rather attempt to argue that it was essentially undisputed that the drivers were bona fide employees. This is not true.

In the first place, the State moved to strike defendant Harden's sworn motion and raised substantial questions as to whether the motion properly swore to any facts. R 1:159. Mr. Harden's motion did not swear to the truth of anything stated to be within his own knowledge but rather purported to attest that parts of depositions of other persons were "true and correct" and established that the drivers were employees of Mr. Harden's companies. SR1:1. The trial court did not rule on that motion to strike.

Although counsel for the State, possibly because the court had not ruled on the motion to strike, acquiesced in the trial court's decision not to rule on the employment issue, the question of whether the drivers were bona fide employees was clearly disputed and just as clearly not resolved. R 2:240, 282-284 (transcript). It was Harden's obligation, not the State's, to obtain a ruling on whether the drivers were employees within the meaning of 26 U.S.C. § 3121(d)(2) and 42 C.F.R. § 1001.952(i), and he failed to do so.

2. No Covered Items Or Services

Harden's brief states that "Harden's drivers were 'employed' to assist their employer in providing 'covered items and services' by "inform[ing]" the parents of Medicaid eligible children of their right to obtain EPSDT dental services for their children and 'transporting' the eligible children to the dental provider." Harden Br. at 20. But "informing" or "transporting" are not covered items or services; they are the responsibility of the State. See 42 U.S.C. § 1396a(a)(43); 42 C.F.R. § 441.62. The drivers did not receive payments "for employment in the provision of covered items or services." They were paid only for the solicitation and referral of eligible children, and on the facts admitted they are not entitled to the federal Safe Harbor.

In support of their contrary claim, defendants also rely on a statement made by HHS OIG in adopting the final Safe Harbor regulations:

> 9. Employees
>
> The proposed exception for employees permitted an employer to pay an employee in whatever manner he or she chose for having that employee assist in the solicitation of program business and applied to only bona fide employee-employer relationships.

56 Red. Reg. 35952 (July 29, 1991) (emphasis added). (App. E, p. 4). This statement was not consistent with the Safe Harbor provision, at least insofar as it would permit payment

specifically for referrals. The final regulation itself, however, like the Safe Harbor provision, makes clear that what is sheltered are payments to an employee "for employment in the provision of covered items or services for which payment may be made in whole or in part under . . . Medicaid. . . ." 42 C.F.R. § 1001.952(i). Neither solicitation of program business nor a referral for a fee is a covered item or service. HHS OIG has not interpreted its Safe Harbor regulation to apply to non-covered items like patient referrals. See n.4 of Letter from D. McCarty Thornton, HHS, to T. J. Sullivan, IRS, of Dec. 22, 1992, available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm>, and 98-9 Op. HHS (July 13, 1998), available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_9.html>. (App. G and H).

A payment for a patient referral, which is not a covered service, therefore violates the federal Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b)(2), just as it violates section 409.920(2)(3), Florida Statutes. Although defendants cast aspersions on the decisions in United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002), and United States v. Starks, 157 F.3d 833 (11th Cir. 1998), they

neither distinguish those cases nor offer contrary authority. In Obert-Hong the physicians were bona fide employees who were paid for covered services and their compensation depended "on the value of the work performed by the individual doctor, not the value of any referrals." 211 F. Supp. at 1050. If the doctors had been paid on the basis of the value of their referrals––as defendants were here––they could not have claimed the Safe Harbor protection.

Defendants dismiss the Eleventh Circuit's interpretation of the Safe Harbor language in Starks as mere dicta. See 157 F.3d at 839. In fact, that interpretation was critical to the court's vagueness ruling and simply reflects a plain meaning reading of the Safe Harbor language––anyone claiming employee status must also be providing covered items or services. The State's position here is not "radical," as defendants put it, but straightforward and supported by two reasoned federal court decisions. Thus, regardless of whether the Safe Harbor provision preempts state law, it does not apply to the admitted facts of this case.

3. The Davita and Sonnenschein Amicus Briefs.

The amici briefs rest on the erroneous assumption that the federal law protects kickback payments to employees for provision of non-covered items and services, here patient

referrals. While the Davita brief does not address the point, the Sonnenschein brief actually states that HHS OIG has never made this limiting distinction. Br. at 14-15. Of course, the plain language of the Safe Harbor provision and the HHS regulation make the distinction. HHS has also made the distinction in the letter and advisory opinion cited supra, as have the federal courts in Starks and Obert-Hong. Like defendants, the amici fail to distinguish these cases. Moreover, Sonnenschein's representation of what Advisory Opinion 04-09 says–-that an employee need not be providing covered services to be entitled to the Safe Harbor--is just wrong. See Brief 15. At page 4 the Advisory Opinion states:

> [W]e conclude that the Proposed Arrangement comes within the language of the statutory exception and regulatory safe harbor for employee compensation, because the compensation will be paid to the Consulting Physicians pursuant to an employment agreement for the furnishing of covered items and services.

Op. HHS (July 15, 2004), available at <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0409.pdf> (emphasis added). (App. I, p. 4).

This opinion makes clear that the Consulting Physicians are providing covered services. Kickbacks for patient referrals are simply not one of those "commercially beneficial" arrangements–-as the Sonnenschein brief puts it–-that the Safe Harbor

provision was intended to protect. See Op. HHS (Nov. 17, 2000), available at <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_7.htm> (cautioning that van drivers' soliciting and offering free transportation to Medicaid patients and being compensated on per patient basis was an abusive arrangement). (App. C, p. 3).

The Sonneschein brief is also critical of the application of section 409.920(2)(e) to rebates and discounts, which has nothing to do with referring Medicaid eligible patients in exchange for remuneration or how the Safe Harbor provision protects employer-employee payments. There is no rebate or discount issue before the Court, and the argument should be disregarded.

III. SECTION 409.920(2)(e), FLORIDA STATUTES, DOES NOT VIOLATE THE FIRST AMENDMENT NOR IS IT UNCONSTITUTIONALLY VAGUE.

Defendants' reliance on State v. Bradford, 787 So. 2d 811 (Fla. 2001), is meritless. The statute at issue in Bradford prohibited the solicitation of business at any time or place for the purpose of making motor vehicle tort claims or claims for personal injury protection benefits. Intent to defraud was not an element of the offense. Defendants' argument that section 409.920(2)(e) similarly prohibits the mere solicitation of

business, and thereby violates the First Amendment, is insupportable. Section 409.920(2)(e) simply prohibits soliciting, offering, paying or receiving remuneration, including a kickback, in return for referring a person for Medicaid-paid services.

Defendants unaccountably make no distinction between "soliciting business" and referring patients for remuneration. Section 409.920(2)(e) does not prevent employers from advertising or employees from soliciting business. It simply prohibits paying employees or anyone else a kickback for every eligible patient they bring in.

Prohibitions on patient brokering are not unusual. If defendants were correct, the federal Anti-Kickback statute would be unconstitutional as well, because it shelters only covered services and soliciting or paying remuneration for a referral is not a covered service. Per-head payments are just as invalid under that statute. Further, under defendants' First Amendment reasoning, sections 817.505(1) and 456.054, Florida Statutes, would also be unconstitutional because they too prohibit paying for patient referrals. Defendants offer no authority that would warrant such results.

Defendants last contend that section 409.920(2)(e) is vague because it does not define when payments are "unlawful

‘remuneration.’” Harden Br. at 49. It is clear from the statute that remuneration is unlawful when solicited, offered, paid or received in return for referring an individual for Medicaid-paid services.

CONCLUSION

The decisions below should be reversed.

Respectfully Submitted,

CHARLES J. CRIST, JR.
ATTORNEY GENERAL

_____
CHRISTOPHER M. KISE
Solicitor General
Florida Bar No. 855545

LOUIS F. HUBENER
Chief Deputy Solicitor General
Florida Bar No. 0140084

LYNN C. HEARN
Deputy Solicitor General
Florida Bar No. 0123633

JASON VAIL
Assistant Attorney General
Florida Bar No. 298824
OFFICE OF THE ATTORNEY GENERAL
Suite PL-01, The Capitol
Tallahassee, FL 32399
850-414-3300

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served by U.S. mail on the following attorneys on this _____ day of October, 2004:

RONALD J. MANTO
2937 SW 27th Avenue
Suite 107
Coconut Grove, FL 33133
Counsel for E. Cortorreal

TONY MOSS
851 NE 118th Street
Miami, FL 33161
Counsel for V. Carter

ANTHONY C. VITALE
799 Brickell Plaza
Suite 700
Miami, FL 33131
Counsel for G. Harden

STEVEN BUSTAMANTE
1481 NW River Drive
Miami, FL 33125
Counsel for Dr. Edward Polsky

MICHAEL BAND
2601 S. Bayshore Drive
Suite 1600
Miami, FL 33133
Counsel for Maria Rodriguez

AUBREY RUDD
7901 SW 67th Avenue
Suite 206
Miami, FL 33143
Counsel for Herbert Lee Goss

ROBERT GODFREY
Office of the Public Defender
1320 NW 14th St.
Miami, FL 33125
Counsel for F. Johnson, B. Madison, B. Smith

M. STEPHEN TURNER, P.A.
KELLY A. O' KEEFE
Broad and Cassel
215 S. Monroe Street, #400
P. O. Drawer 11300
Tallahassee, FL 32302
Counsel for DaVita, Inc., Fresenius Medical Care Holdings, Inc. d/b/a/ Fresenius Medical Care North America and Gambro Healthcare, Inc.

GABRIEL L. IMPERATO, P.A.
Broad and Cassel
500 East Broward Blvd., #1130
Ft. Lauderdale, FL 33394
Counsel for DaVita, Inc., Fresenius Medical Care Holdings, Inc. d/b/a/ Fresenius Medical Care North America and Gambro Healthcare, Inc

ROBERT COLUMBE, Esq.
19 West Flagler Street, Ste 720
Miami, FL 33130
Attorney for Appellee Flora Johnson

MARK SHUMAKER, Esq.
640 N.W. 15th Avenue
Boca Raton, FL 33486
Attorney for Appellee Edward Polsky

CHARLES WENDER, Esq.
190 West Palmetto Park Road
Boca Raton, FL 33432
Attorney for Dr. Edward Polsky

JANE HYATT THORPE, Esq.
Sonnenschein, Nath & Rosenthal, LLP
1301 K Street, N.W.
Suite 600, East Tower
Washington, D.C. 20005
Attorneys as Amicus Curiae in Support of Appellee Gabriel Harden, et al.

G. RICHARD STRAFER, P.A.
2400 South Dixie Highway
Suite 200
Miami, Florida 33133
Attorney for Appellee, Gabriel Harden

MAX R. PRICE, Esq.
Max R. Price, P.A.
6701 Sunset Drive, Suite 104
Miami, FL 33143
Attorneys for Joel M. Berger, D.D.S.

_____
CHRISTOPHER M. KISE

CERTIFICATE OF COMPLIANCE

I hereby certify that the State of Florida's Reply Brief complies with the font requirements of Fla. R. App. P. 9.210(a)(2), in that this Brief uses Courier New 12 point font.

_____
CHRISTOPHER M. KISE