IN THE SUPREME COURT OF FLORIDA

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

APPELLANT STATE OF FLORIDA'S INITIAL BRIEF

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 **ATTORNEY** THE

The Capitol, Suite PL-01 Tallahassee, FL 32399-1050

GENERAL

(850) 414-3681 Counsel for Appellant, State of Florida **TABLE OF CONTENTS**

TABLE OF	AUTHORITIES iii
STATEMEN	T OF THE CASE AND FACTS 1
The In	nformation
The M	fotions to Dismiss
The T	rial Court's Order
The D	District Court's Decision
STANDARI	O OF REVIEW
SUMMARY	OF THE ARGUMENT
ARGUMEN	Т13
I.	THE FEDERAL MEDICAID ANTI-KICKBACK STATUTE AND THE "SAFE HARBOR" PROVISION DO NOT PREEMPT SECTION 409.920(2)(e)
А.	Section 409.920(2)(e) Is Not Inconsistent With The Structure And Purpose Of The Federal Law
В.	Congress Intended That The States Enforce Their Own Fraud Laws
C.	The Lower Courts' Analysis Does Not Support Preemption
	1. Defendants did not establish the existence of a bona fide employment relationship

	2.	Solicitation and referral are not covered items or services.	21
	3.	The defendants were not charged with negligent or inadvertent conduct	24
II.	SCHE	SAFE HARBOR STATUTE DOES NOT TECT HARDEN'S "PER-HEAD" PAYMENT EME FOR SOLICITATION AND REFERRAL OF IBLE MEDICAID PATIENTS	27
III.	INVA	TRIAL COURT'S OTHER GROUNDS FOR ALIDATING SECTION 409.920(2)(e) ARE ITLESS	31
A.		on 409.920(2)(e) Does Not Violate The First dment.	31
	1.	Section 409.920 does not inhibit First Amendment rights	31
	2.	The defendants' employer waived its First Amendment right to solicit Medicaid clients	32
B.	The S	tatute Is Not Void For Vagueness	34
CONCLUSI	ON .		37
CERTIFICA	TE OF	F SERVICE	38
CERTIFICA	TE OF	F COMPLIANCE	40
APPENDIX			

TABLE OF AUTHORITIES

CASES

Agency for Health Care Admin. v.
Baker County Medical Services Inc., 832 So. 2d 841 (Fla. 1st DCA 2002)
<u>Armstrong v. Harris</u> , 773 So. 2d 7 (Fla. 2000) 8
Brockett v. Spokane Arcades, Inc., 472 U.S. 491 (1985) 26
Bryan v. United States, 524 U.S. 184 (1998) 24
<u>California v. ARC America Corp.</u> , 490 U.S. 93 (1989) 15
Capital City Country Club v. Tucker,
613 So. 2d 448 (Fla. 1993)
Commonwealth of Pennsylvania v. Morris,
575 A.2d 582 (Pa. Super. 1990),
<u>aff'd</u> , 601 A.2d 806 (Pa. 1992) 17
D.H. Overmeyer Co., Inc. of Ohio v. Frick Co.,
405 U.S. 174 (1972)
Dalton v. Little Rock Family Planning Services,
516 U.S. 474 (1996)
Execu-Tech Bus. Sys. v. New Oji Paper Co.,
752 So. 2d 582 (Fla. 2000)
Gade v. National Solid Wastes Mgmt., 505 U.S. 88 (1992) 13,15
<u>Gillman v. Butzloff</u> , 22 So. 2d 263 (Fla. 1945) 33
Hanlester Network v. Shalala, 51 F.3d 1390 24,32

Harris v. McRae, 448 U.S. 297 (1980) 14
<u>Lasky v. State Farm Insurance Co.</u> , 296 So. 2d 9 (Fla. 1974)
<u>Maryland v. Louisiana</u> , 451 U.S. 725 (1981) 14
New York State Dep't of Social Services v. Dublino, 413 U.S. 405 (1973)
Paragould Cablevision Inc. v. City of Paragould, Arkansas,930 F.2d 1310 (8th Cir. 1991)
Pharmaceutical Research and Mfrs. of America v. Walsh,538 U.S. 644 (2003)14
Pharmaceutical Research and Mfrs. v. Concannon,249 F.3d 66 (1st Cir. 2001)14,26
<u>Rice v. Norman Williams Co.</u> , 458 U.S. 654 (1982) 26
<u>State v. Bradford</u> , 787 So. 2d 811 (Fla. 2001) 31
<u>State v. Brake</u> , 796 So. 2d 522 (Fla. 2001) 35
<u>State v. Hogan</u> , 387 So. 2d 943 (Fla. 1980) 26
State v. Pasko, 815 So. 2d 680 (Fla. 2d DCA 2002) 8
State v. Riker, 376 So. 2d 861 (Fla. 1979) 35
<u>State v. Yocum</u> , 186 So. 448 (Fla. 1939) 9
<u>Styron v. State</u> , 662 So. 2d 965 (Fla. 1st DCA 1995) 8
<u>United States v. LaHue</u> , 261 F.3d 993 (10th Cir. 2001)

<u>United States v. McClatchey</u> , 217 F.3d 832 (10th Cir. 2000) 30
United States v. Neufeld, 908 F. Supp. 491 (S.D. Ohio)
United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002) passim
<u>United States v. Polin</u> , 194 F.3d 863 (7th Cir. 1999) 30
<u>United States v. Salerno</u> , 481 U.S. 739 (1987) 26
<u>United States v. Starks</u> , 157 F.3d 833 (11th Cir. 1998) passim
Wash. Dep't of Soc. & Health Services v. Bowen,815 F.2d 549 (9th Cir. 1987)14

FEDERAL STATUTES

26 U.S.C. 3121(d)(2) 5, 6
42 U.S.C. § 1320a-7b(b) 26
42 U.S.C. § 1320a-7b(b)2 4,18
42 U.S.C. § 1320a-7b(b)(3)(B) passim
42 U.S.C. § 1396 (2000) 15, 16
42 U.S.C. § 1396a
42 U.S.C. § 1396a(a)(43) 22
42 U.S.C. § 1396a(a)(27)
42 U.S.C. § 1396a(61)

42 U.S.C. § 1396b(q)		16,17
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FLORIDA STATUTES

Section 409.905	•	• •	•••	•	•	• •	•	•	•	•	•••	•	•	 •	•	• •	 •	•••	•	•	••	•	•	 •	•	•••	•	•	• •	•	•	• •	22	2
Section 409.907				•	•		•	•	•	•		•	•	 •		• •			•	•	•••	•	•	 •		•••	•	•	• •	•	•	25	5,33	3
Section 409.920		• •			•		•	•		•		•	•	 •	•	• •	 •		•	•		•	•	 •	•		•	•	• •	•	ŀ	pas	sin	n

FLORIDA RULES OF CRIMINAL PROCEDURE

Rule 3.190(c)		2
---------------	--	---

FLORIDA RULES OF APPELLATE PROCEDURE

Rule 9.030(a)(1)(A)(ii)		
-------------------------	--	--

ADMINISTRATIVE REGULATIONS

42 C.F.R. § 1001.952		5,19
----------------------	--	------

OTHER AUTHORITIES

H.R. R	ept. 92-231,	92nd Cong.,	2d Sess.,	reprinted	in		
1972 U	J.S. Cong. a	nd Admin. N	ews 5094			 	. 18

H.R. Rept. 95-393, 1977 U.S. Code Cong. & Admin. News (1st Sess.) at 3056
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56 Fed. Reg. 35952,35957 (July 29, 1991) 19,22
64 Fed. Reg. 63504, 63506 (Nov. 19, 1999) 19
Webster's Ninth New Collegiate Dictionary (1983)
Fla. CS/SB 1064, § 8 (2004) 6
Rules 59G-4.060 and 59G-4.330, Fla. Admin. Code

STATEMENT OF THE CASE AND FACTS

The State appeals a decision of the Third District Court of Appeal declaring the Anti-Kickback provision of Florida's Medicaid Provider Fraud Statute, section 409.920(2)(e), Florida Statutes, unconstitutional under the Supremacy Clause of the United States Constitution. Section 409.920(2)(e) makes it unlawful to pay any remuneration in return for the referral of a person for the furnishing of a Medicaid reimbursed item or service.¹ The core issue is whether the payment of a "per-head" fee by a Medicaid provider to individual drivers to solicit and refer Medicaid-eligible children to a dental facility constitutes an illegal referral or kickback under section 409.920(2)(e).

The Information

¹Section 409.920(2)(e), Florida Statutes, provides:

(2) It is unlawful to:

⁽e) Knowingly solicit, offer, pay, or receive any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

In December 2000, the State filed a nine-count information charging Gabriel Harden and eight other individuals who were allegedly "employed by or associated with Dental Express Dentists" (Dental Express) with conspiracy, racketeering, and Medicaid fraud under section 409.920(2)(e), Florida Statutes. R1: 1-6. The State alleged the defendants engaged in a "pay for patients" scheme in which individuals received payments in exchange for referring Medicaid patients to Dental Express. The alleged scheme involved \$25 "per-head" payments to at least six people -- the drivers -- to solicit and refer Medicaid-eligible children for treatment at defendants' dental facility under the state Medicaid program.

The Motions To Dismiss

Defendant Harden filed two motions to dismiss the information pursuant to Rule 3.190, Florida Rules of Criminal Procedure. These two motions were adopted by the other defendants. SR1: 20-24. Contrary to Rule 3.190(c), the first motion, filed October 4, 2002, was premised on various factual allegations but was unsworn. R1:61.

Harden filed a sworn motion to dismiss the information on October 21, 2002. SR1:1. This motion sought to establish, among other things, that the drivers had a "bona fide employer-employee relationship" with Harden's companies as contemplated by the federal safe harbor statute. (Harden himself was not a dentist.) The State moved to strike the sworn motion to dismiss and also filed a sworn traverse/demurrer. R1:159 and SR1:14.

Harden's first, unsworn motion did not deny the drivers were paid in cash on a per-head basis. The second, sworn motion conceded as much. SR1:1 ¶ 5e. See <u>also</u> R2: 217-218 (admitting cash payments in amount of \$25 per head). The State's response to the unsworn motion did not concede Harden's drivers were true employees. R1:168. <u>See also</u> R2:238 (transcript). The trial court deferred any ruling on whether the drivers were independent contractors or employees of Dental Express. R2:282-284.

The Trial Court's Order

The trial court did not address the State's motion to strike the sworn motion, and its final order gave no indication it considered Harden's sworn motion. The final order referred specifically to the unsworn motion and granted it on several constitutional grounds. R1:170.

The final order clearly rests on the assumption that Harden's business, Dental Express, was the employer of the drivers used to solicit and refer Medicaid-eligible children to Harden's facility. R1:170-171. The order refers repeatedly to "employer-employee payments." <u>Id.</u> at 174, 175, 177. Thus, even though the court deferred

ruling on the issue, the court must have assumed the drivers were "employees" regardless of how they were paid.

The trial court held federal law and regulations preempted section 409.920(2)(e). The court opined that the language of the Medicare/Medicaid Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b)(2), could be "construed to prohibit all types of wages (as a form of 'payment') by a Medicaid provider to its employees for solicitation of even perfectly legitimate business for the provider."² <u>Id.</u> at 177.

The court concluded, however, that the so-called federal "safe-harbor" provision, 42 U.S.C. § 1320a-7b(b)(3)(B), carved out an exception that "allow[ed] a

²42 U.S.C. § 1320a-7b(b)(2) provides:

(b) Illegal remuneration

* * *

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person-

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program****

shall be guilty of a felony****

Medicaid provider to solicit business through its own paid employees."³ Thus, even though solicitation and referral of patients are not items or services for which payments may be made under Medicaid, the court held that federal law permitted a Medicaid provider to pay any "employee" (the court did not address the meaning of "employee" or "bona fide employment relationship") in exchange for the solicitation and referral of Medicaid patients. The court also found support for its ruling in 42 CFR § 1001.952(i).⁴

³42 U.S.C. § 1320a-7b(b)(3)(B) provides:

(3) Paragraphs (1) and (2) shall not apply to---

(B) any amount paid 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; (e.s.)

⁴This regulatory "safe harbor" merely reiterates the "safe harbor" statute and provides:

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion.

(i) Employees. As used in section 1128B of the Act, "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2). (e.s.)

The court therefore held section 409.920(2)(e) was preempted because it "stood as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." R1:177. Beyond stating its belief that Florida has a more stringent fraud standard, the trial court did not explain how the Florida law thwarted any purpose or objective of the federal law.

The trial court also found federal law preempted the Florida statute because of different <u>mens rea</u> requirements. R1: 184-186. Section 409.920(2)(e) requires that a defendant act "knowingly" as defined in Section 409.920(1)(d), but the federal Anti-Kickback statute requires "willfulness."⁵ The court decided Congress intended to exclude negligent conduct but that Florida law includes it, thereby frustrating Congress' intent. R1:186.⁶

⁵Section 409.920(1)(d), Florida Statutes, defines "knowingly":
(d)"Knowingly" means done by a person who is aware or 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.

⁶The legislature amended section 409.920(2)(e) in the 2004 regular session to conform with the federal law. <u>See</u> Fla. CS/SB 1064, § 8 (2004). As of the filing of this brief, the legislation has been enrolled but not presented to the Governor.

²⁶ U.S.C. § 3121(d)(2) says "employee" should be defined according to common law. The trial court engaged in no inquiry on this question.

The trial court also held section 409.920(2)(e) violated the First Amendment by prohibiting all "solicitation" for any purpose, including totally lawful conduct. R1:186-188.

Finally, the trial court held section 409.920(2)(e) was "unconstitutionally vague for failing to define the operative term 'unlawful remuneration.'" R1:188. The court found the term vague because it did not give fair notice to a Medicaid provider that paying its employees to solicit was unlawful. <u>Id.</u> Section 409.920(2)(e), however, does not contain the term "<u>unlawful</u> remuneration." It refers only to "remuneration."

The District Court's Decision

The Third District affirmed the trial court but on only two grounds. First, the Third District held the federal "safe harbor" in 42 U.S.C. § 1320a-7b(b)(3)(B) preempted section 409.920(2)(e) in its entirety. The federal safe harbor, the court held, "protects employer-employee payments for the provision of covered items or services from criminal prosecution." Slip op. at 6. The court said both federal and state law require states participating in Medicaid to provide transportation as a covered service. <u>Id</u>. Thus, because Florida law permitted a prosecution for paying for a covered service -- transportation -- state law obstructed Congress' intention to exempt prosecutions for such payments. In reaching this result, the Third District ignored the

fact the information charged defendants with making payments for solicitation and referral, not transportation.

Second, the Third District held federal Medicaid law also preempted section 409.920(2)(e)'s <u>mens rea</u> requirement. The court found Florida law allows prosecution for negligent conduct, which federal law does not, thus frustrating Congress' intentions to prohibit convictions for negligent acts. <u>Id.</u>

The decision of the Third District effectively renders section 409.920(2)(e) facially invalid.

The State filed a timely notice of appeal on April 2, 2004, seeking direct review of the Third District's decision. <u>See</u> Rule 9.030(a)(1)(A)(ii), Fla.R.App.P.

STANDARD OF REVIEW

The standard of review governing decisions of law is <u>de novo</u>. <u>Execu-Tech</u> <u>Bus. Sys. v. New Oji Paper Co.</u>, 752 So. 2d 582 (Fla. 2000); <u>Armstrong v. Harris</u>, 773 So. 2d 7 (Fla. 2000). The standard for appellate review for the pretrial order of dismissal in this case is also <u>de novo</u>. <u>See State v. Pasko</u>, 815 So. 2d 680, 681 (Fla. 2d DCA 2002) (citing <u>Styron v. State</u>, 662 So. 2d 965 (Fla. 1st DCA 1995)).

Because the courts below declared section 409.920(2)(e) unconstitutional, this Court must find beyond a reasonable doubt that the law is invalid. <u>Lasky v. State</u> <u>Farm Insurance Co.</u>, 296 So. 2d 9, 15 (Fla. 1974). All doubts as to constitutionality are to be resolved in favor of the statute. <u>State v. Yocum</u>, 186 So. 448, 451 (Fla. 1939). Courts must interpret statutes in such a manner as to uphold their constitutionality if it is reasonably possible to do so. <u>Capital City Country Club v.</u> <u>Tucker</u>, 613 So. 2d 448, 452 (Fla. 1993).

SUMMARY OF THE ARGUMENT

I. Section 409.920(2)(e) is not preempted by the federal Medicaid Anti-Kickback statute and the "safe harbor" provision. There is a presumption against preemption which applies when the state and federal governments are engaged in a program that exists within a complementary framework, such as the Medicaid program, and that presumption applies with particular force to the circumstances of this case.

Even assuming section 409.920(2)(e) imposes a more stringent control on kickback payments and applies to "merely negligent" conduct, there should be no finding of preemption for three salient reasons. First, federal laws clearly prohibit kickback payments. A stricter state standard does not frustrate the "full purposes and objectives" of the federal laws which are also to prevent fraud and abuse, particularly kickbacks. Second, Congress clearly intended that the states enforce their own laws

on fraud, and has authorized them to do so. Thus, Congress itself did not think the purposes and objectives of federal law would be frustrated by the enforcement of state law. Third, defendants were not charged with "merely negligent" conduct, and the lower courts did not attempt to explain how a scheme to pay for patient referrals could be negligent conduct. They simply assumed someone at some time might be charged with an inadvertent violation of section 409.920(2)(e). The lower courts erred as a matter of law because preemption may not be based on a hypothetical or potential conflict between state and federal law; state law is displaced only to the extent of actual conflict with federal law. Moreover, defendants may not challenge the application of a statute to conduct with which they have not been charged.

Additionally, the Defendants are not entitled to claim the protection of the safe harbor provision because that statute applies only to "bona fide employment relationships" and defendants did not establish that their per-head payment scheme for the drivers constituted a bona fide employment relationship. Furthermore, solicitation and referral of patients is not a "covered item or service" under the safe harbor provision. Defendants did not establish either that they paid for transportation or that transportation was a covered item or service for which the State would pay in the circumstances of this case.

II. The safe harbor exception to the Medicaid Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b)(3)(B), does not permit employee kickback payments such as those at issue here. The trial court erred in its interpretation of that law and the decision in United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp 2d 1045 (N.D. Ill. 2002). As Obert-Hong makes clear, the safe harbor provision permits compensation to employees based on the value of their professional services, but it does not permit compensation for patient referrals. This is consistent with the "one purpose" rule adopted by at least four federal circuits. Under that rule, a Medicaid provider violates the federal Anti-Kickback statute if one purpose of a payment to a third party, non-employee is to induce patient referrals, even if the payment arguably compensates for a covered service. The trial court's interpretation of the safe harbor provision creates the exception that swallows the rule, and it was not approved by the Third District. Accordingly, because the federal Anti-Kickback statute would bar exactly the kickback payments made here, the trial court erred in finding preemption.

III. Section 409.920(2)(e) does not violate the First Amendment. This section merely prohibits the defendants from paying compensation in direct exchange for patient referrals, not from soliciting business generally nor engaging in routine advertising and marketing. Further, like the federal anti-kickback statute, this statute merely regulates economic conduct and does not implicate a constitutional right. In

any event, constitutional rights may be waived. Any First Amendment right the defendants had to solicit Medicaid clients in exchange for compensation was waived by Dental Express as part of its provider agreement with the State. In that agreement Dental Express agreed to comply fully with all state and federal laws governing the Medicaid program.

Finally, the trial court's finding that section 409.920(2)(e) is unconstitutionally vague was unfounded. This finding pertained to the phrase "unlawful remuneration," a term that does not appear in section 409.920(2)(e). Instead, the phrase used in this section is "any remuneration." There is nothing unclear about this term. Furthermore, the phrase "unlawful remuneration" appears in the federal anti-kickback statute, and federal courts have repeatedly upheld the constitutionality of this term in the face of vagueness challenges.

ARGUMENT

I. THE FEDERAL MEDICAID **ANTI-KICKBACK** THE **"SAFE STATUTE** AND HARBOR" DO NOT PREEMPT PROVISION SECTION 409.920(2)(e).

A. Section 409.920(2)(e) Is Not Inconsistent With The Structure And Purpose Of The Federal Law.

The Supreme Court has recognized three discrete categories of preemption under the Supremacy Clause: (1) express preemption, where a federal statute contains "explicit preemptive language"; (2) field preemption, in which the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it"; and (3) implied conflict preemption, in which "compliance with both federal and state regulations is a physical impossibility" or where state law "stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress." Gade v. National Solid Wastes Mgmt., 505 U.S. 88, 98 (1992) (quotations and citations omitted). Here the lower courts erroneously held Florida's statute making criminal a Medicaid provider's per-head cash payments to "employees" for soliciting and referring Medicaid patients stood as an obstacle to the accomplishment of the purpose and objectives of the federal-state Medicaid program.

Proper application of preemption principles does not lead to the conclusion that Florida law stands as an obstacle to federal ends. First, preemption analysis begins with the "basic assumption that Congress did not intend to displace state law." Marvland v. Louisiana, 451 U.S. 725, 746 (1981). This presumption applies with all the more force to joint or coordinate state and federal programs.⁷ Pharmaceutical Research and Mfrs. of America v. Walsh, 538 U.S. 644, 666 (2003) ("The presumption against federal preemption of a state statute designed to foster public health . . . has special force when it appears . . . that the two governments are pursuing common purposes) (citations omitted); New York State Dep't of Social Services v. Dublino, 413 U.S. 405, 421 (1973) ("Where coordinate state and federal efforts exist within a complementary framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one."). Accord Pharmaceutical Research and Mfrs. of America v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001) (quoting Dublino); Wash. Dep't of Soc. & Health Servs. v. Bowen, 815 F.2d 549, 557 (9th Cir. 1987) (relying on <u>Dublino</u> and holding that because the Medicaid program

⁷Medicaid is a cooperative state-federal program in which each participating state designs and implements its own Medicaid program subject to certain structures established by federal law. <u>See 42 U.S.C. § 1396a</u> (prescribing general requirements of state Medicaid plan). <u>See also Harris v. McRae</u>, 448 U.S. 297, 309 (1980)(referring to Medicaid program as a "system of cooperative federalism").

consists of coordinated state and federal efforts that exist within a complementary framework, agency regulations do not preempt state community property law). Furthermore, when Congress legislates in a field traditionally occupied by the states, the states' police powers will not be presumed to have been superceded "unless that is the clear and manifest purpose of Congress." <u>California v. ARC America Corp.</u>, 490 U.S. 93, 101 (1989).

Importantly, preemption does not rest on minor differences between the state and federal laws. The Supreme Court stated explicitly in <u>Gade</u> that "[o]ur ultimate task in any preemption case is to determine whether state regulation is consistent with the structure and purpose of the [federal] statute *as a whole*." 505 U.S. at 98 (emphasis added).⁸ The analysis and decisions of the two lower courts consider neither the structure and purpose of the relevant Medicaid law as a whole nor the role of the state in enforcing what is, in the end, a state-administered program. Indeed, the primary purpose of Medicaid is to enable each state, "as far as practicable under the conditions in such state," to provide medical services to those "whose income and

⁸As the Court further stated in <u>Gade</u>, "Looking to 'the provisions of *the whole law and to its object and policy*,' we hold that nonapproved state regulation of occupational safety and health issues for which a federal standard is in effect is impliedly preempted as in conflict with the full purposes and objectives of the OSH Act." 505 U.S. at 98 (internal quotation marks and citation omitted) (emphasis added).

resources are insufficient to meet the costs of necessary medical services," 42 U.S.C. § 1396 (2000), and to provide such medical services with minimal losses to fraud and abuse.⁹

Applying these principles does not lead to the conclusion that section 409.920(2)(e) is fatally at odds with the purpose and structure of the Medicaid law. It is certainly possible for a Medicaid provider to comply with both the federal fraud law and section 409.920(2)(e), and defendants have never contended otherwise. Defendants have only to refrain from paying "employees" to solicit and refer Medicaid-eligible patients on a per-head basis. For the state to require that defendants not engage in such conduct hardly stands as an obstacle to the achievement of any significant federal objective. Federal law, like state law, seeks to curtail fraud and abuse, and it regards kickback payments as malum in se. United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998).

⁹A required element of any state plan seeking federal assistance, unless found not cost effective, is a medicaid fraud and abuse control unit. 42 U.S.C. § 1396a(61). The function prescribed for such a unit is "the investigation and prosecution of violations of all applicable <u>state laws regarding any and all aspects of fraud</u> in connection with (A) any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this subchapter: . . ." 42 U.S.C. § 1396b(q) (emphasis added).

The fact Florida may have a more stringent fraud law no more commands a preemption finding than would the fact state law might provide a more stringent penalty than a corresponding federal law. One court, noting that "[u]nder our federalism, the states have the principal responsibility for defining and prosecuting crimes," rejected the contention that state prosecution of state law on theft of welfare checks was preempted by the Social Security Act. Commonwealth of Pennsylvania v. Morris, 575 A.2d 582 (Pa. Super. 1990), <u>aff'd</u>, 601 A.2d 806 (Pa. 1992). As with Medicaid, the <u>Morris</u> court observed that "[t]he heart of the Social Security Act is the provision of federal funding to aid, not usurp, state involvement . . ." <u>Id.</u> at 585. The fact state and federal law provided for different penalties for the same offense "has never prevented dual federal and state jurisdiction for criminal prosecutions . . . let alone triggered preemption." <u>Id.</u> at 586 (internal citation omitted).

Defendants were charged here with "knowingly" engaging in a scheme to pay for patient referrals. That section 409.920(2)(e) does not require proof of "willfulness" is not a difference that commands a finding of preemption, particularly when Congress intended that the states enforce their own laws on fraud.

B. Congress Intended That The States Enforce Their Own Fraud Laws.

Federal law manifests no intent to displace the states' enforcement of their own laws or limit the states' concept of fraud to that embodied in federal law or regulations. To the contrary, Congress would not have authorized Medicaid fraud units under 42 U.S.C. § 1396 b(q) to prosecute "violations of all applicable state laws regarding any and all aspects of fraud," laws bound to differ not only among the states but also with federal law, had it intended preemption. To the contrary, it is beyond dispute Congress intended for the states to take primary enforcement responsibility and to do so in accordance with their own state laws addressing fraud. Congress enacted the Medicare/Medicaid Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b)(2), in 1972. In making specific federal crimes of "such practices as the soliciting, offering or accepting of kickbacks or bribes, including the rebating of a portion of a fee or charge for a patient referral, involving providers of health care services," the committee report made clear that these provisions "would be in addition to and not in lieu of any other penalty provisions in state or federal law." H.R. Rept. No. 92-231, 92nd Cong., 2d Sess., reprinted in 1972 U.S. Cong. and Admin. News 5094 (emphasis added).

In 1977 Congress added the "safe harbor" provision which shielded from prosecution "any amount paid by an employer to an employee (who has a bona fide relationship with such employer) for employment in the provision of covered items or services." 42 U.S.C. § 1320a-7b(b)(3)(B)(emphasis added).¹⁰ When promulgating the safe harbor regulation, 42 CFR § 1001.952, the federal Department of Health and Human Services clarified that the federal law and the proposed regulation did not preempt state enforcement laws:

Comment: Two commentators requested that the OIG clarify the relationship between the statute and various State laws.

Response: Issues of state law are completely independent of the federal anti-kickback statute and these regulations. There is no federal preemption provision under the statute. Thus, conduct that is lawful under the federal anti-kickback statute or this regulation may still be illegal under State law. Conversely, conduct that is lawful under State law may still be illegal under the federal anti-kickback statute.

56 Fed. Reg. 35952, 35957 (July 29, 1991).¹¹

¹⁰As stated in H.R. Rept. 95-393, 1977 U.S. Code Cong. & Admin. News (1st Sess.) at 3056:

The bill would define the term "any remuneration" broadly to encompass kickbacks, bribes, or rebates which may be made directly or indirectly, overtly or covertly, in cash or in kind (but would exclude any amount paid by an employer to an employee for employment in the provision of covered items or services.)

¹¹When undertaking further rulemaking in 1999 to address safe harbors for certain managed care arrangements, HHS again emphasized that:

Compliance with a safe harbor only provides protection from the Federal anti-kickback criminal statute Safe harbors do not apply to other laws, such as State licensure laws, antitrust laws or other Federal and State health care fraud laws.

The text, structure, and legislative history of the federal Medicaid fraud and abuse statutes, supported by HHS, could not more clearly reflect Congress' intention to promote independent state enforcement of the states' own criminal laws. Federal laws on fraud and abuse are intended to supplement state laws, not to displace or preempt them. Congress plainly did not believe its purposes would be frustrated by enforcement of state laws.

C. The Lower Courts' Analysis Does Not Support Preemption.

Both the lower courts ignored the indisputable fact Congress intended the states to enforce their own fraud laws. The trial court's reasoning, for all its length, simply concludes the payments at issue here are not made criminal under federal law and therefore must be permitted by state law, and if they are not, preemption applies. This approach not only short-circuits principled application of the preemption doctrine and ignores congressional intent, but also avoids examination of the safe harbor language.

1. Defendants did not establish the existence of a bona fide employment relationship.

Both 42 U.S.C. § 1320a-7b(b)(3)(B) and the administrative regulation apply only to "bona fide employment relationships." Such a relationship is a defense that must be proved, and the State denied it existed. The trial court deferred ruling on this

⁶⁴ Fed. Reg. 63504, 63506 (Nov. 19, 1999).

question. R2: 282-284. Because the defendants failed to establish this critical element, the trial court was in no position to decide whether the safe harbor statute preempted Florida law. For this reason alone, the decisions below should be vacated.

2. Solicitation and referral are not covered items or services.

The plain language of the safe harbor statute and rule also requires that the employment relationship be for employment in the "furnishing of any item or service for which payment may be made in whole or in part" under Medicaid.¹² Drivers do not furnish an item or service for which Medicaid pays when they solicit and refer eligible patients. The drivers were not paid for furnishing any "covered item or service." They therefore cannot claim the protection of the safe harbor provision as employees. <u>United States v. Starks</u>, 157 F.3d 833, 839 (11th Cir. 1998) (upholding kickback convictions and stating that "even if [defendants] believed they were bona fide employees, they were not providing 'covered items or services'"). The trial court's order never explains how an employment relationship involving solicitation and

¹²The State's response to the defendants' motion to dismiss argued that recruiting patients was not a covered item or service. R1:165.

referral of eligible patients, paid for on a per-head basis, fits within the safe harbor provision.¹³

The Third District's analysis fails to shore up these gaps in logic. Like the trial court, it made no effort to determine what the term "bona fide employment relationship" meant. It did not even attempt to distinguish the <u>Starks</u> decision or identify what "covered item or service" a hired driver would be furnishing when engaged in the solicitation and referral of patients. The best it could say was that "[t]he federal medicaid statutes require participating states to provide transportation to those eligible for dental services," citing 42 U.S.C. § 1396a(a)(43), and section

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 <u>and applied only to bona fide employee-employer relationships</u>.

¹³To the extent the trial court dealt with this question it simply referred to what it called the "intended broad scope of the protection" as evidenced by agency commentary, R1:179, but only partially quoting that commentary. In full, the comment stated:

Final Rule, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991). The trial court did not quote the underscored language. The State does not concede this comment would shelter the scheme at issue here, but even if the safe harbor statute may be read so broadly, the HHS OIG, in the same commentary, opined that there was no preemption of state law and that conduct that was lawful under the federal statute and regulation "may still be illegal under State law." 56 Fed. Reg. 35957.

409.905(12), Florida Statues. Slip Op. at 6. Subsection (a)(43)(B), however, only requires the state plan to arrange "for the provision of such screening services in all cases where they are requested." Under section 409.905(12), including the introductory paragraph of that section, payment for transportation may be made only in accordance with AHCA policies and for mandatory and medically necessary services. This subsection cannot be reasonably construed to require providing transportation to any and every Medicaid-eligible patient without regard for any showing of need.

Moreover, the record does not support the slightest inference that AHCA policies would permit payment to defendants' drivers. Indeed, AHCA rules distinguish between "dental services providers enrolled in the Medicaid program" and "transportation services providers enrolled in the Medicaid program." <u>See</u> Rules 59G-4.060 and 59G-4.330, Fla. Admin. Code. (App. C and D) Defendants have never even claimed that they, their drivers or Dental Express are a "transportation service provider enrolled in the Medicaid program" entitled to reimbursement for transportation under the Handbook criteria these rules adopt by reference. Thus, contrary to the Third District's apparent assumption, neither of the provisions it cited would mandate compensation to Medicaid dentists (or defendants' drivers) for transportation costs.

In any case, the offense charged here is payment of a per-head fee for solicitation and referral of patients, not the furnishing of transportation. Nothing in the safe harbor statute or the regulation suggests solicitation and referral is a covered item or service. The safe harbor provisions therefore do not apply.

3. The defendants were not charged with negligent or inadvertent conduct.

The lower courts' <u>mens</u> <u>rea</u> analysis in no way strengthens the case for preemption. While the federal Anti-Kickback statute requires an offender act "knowingly and willfully," the Supreme Court has held that "willful" means only that an offender knows his conduct is unlawful. Slip Op. at 6-7 (citing <u>Bryan v. United</u> <u>States</u>, 524 U.S. 184, 192 (1998). As the <u>Starks</u> court points out in the context of the Anti-Kickback statute, it is not necessary that an offender know his conduct violates a specific law. 157 F.3d at 838 and n. 6. Furthermore, the decision in <u>Hanlester</u> <u>Network v. Shalala</u>, 51 F.3d 1390, 1399 n. 16 (9th Cir. 1995), relied on by the lower courts, concluded that Congress intended to shield from prosecution "only those whose conduct 'while improper, was inadvertent.'" <u>Id.</u> at 1399 n. 16 (quoting H.R. No. 96-1167, 96th Cong. 2d Sess. 59 (1980), U. S. Code Cong. & Admin. News, (1980) 5526, 5572).

The Third District found that section 409.920(1)(d) allowed prosecution of an offender for "mere negligence" and summarily concluded the Florida law was an obstacle to the "full purposes and objectives of Congress," and hence preempted. Slip Op. at 7.

This conclusion was not explained by the court nor does it stand as self-evident. The court's leap in logic ignores Congress' intent, acknowledged by HHS, to allow states to enforce their own fraud laws. The fact Florida's law might be more stringent than its federal counterpart does not thwart Congress' purpose, which is also to deter fraud and abuse, especially in the form of kickbacks, which are regarded as <u>malum in se</u>, not <u>malum prohibitum</u>. <u>Starks</u>, 157 F.3d at 838. Consistent with this understanding, Medicaid providers must agree to "comply fully" with state law. <u>See</u> § 409.907(1) and (2), Fla. Stat.

More importantly, however, the defendants here are not charged with anything like negligent or inadvertent conduct. The violations charged are not isolated, incidental, accidental, or the product of "mere negligence." They were part of a pervasive and ongoing scheme to solicit and pay for patient referrals in violation of Florida law. Defendants were, in the terminology of section 409.920(1)(d), aware of the nature of their conduct and its intended result. Moreover, the statute does not require that negligent conduct be prosecuted. But even if it may be said that "negligent" conduct should be sheltered, that is no ground for the <u>facial</u> invalidation of section 409.920(2)(e).

By finding as it did the statute was completely preempted when defendants were not charged with anything like negligent conduct, the Third District has rendered it facially invalid. This is error because, as the federal First Circuit has held, a facial challenge must establish that a statute is not valid under any set of circumstances, and the existence of a hypothetical or potential conflict is insufficient to warrant preemption of a state statute. Pharmaceutical Research and Mfrs. v. Concannon, 249 F.3d 66, 77 (1st Cir. 2001) (citing United States v. Salerno, 481 U.S. 739, 745 (1987), and Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)). In preemption cases state law is displaced only to the extent of actual conflict with federal law. <u>Dalton v. Little Rock</u> Family Planning Services, 516 U.S. 474, 476 (1996). "The rule [is] that a federal court should not extend its invalidation of a state statute further than necessary to dispose of the case before it." Id. at 476 (quoting Brockett v. Spokane Arcades, Inc., 472 U.S. 491, 502 (1985)). This limitation is closely akin to another principle fatal to the ruling below: A person may not challenge that portion of a criminal statute that does not affect him. State v. Hogan, 387 So. 2d 943 (Fla. 1980). Thus given the allegations in the information, the courts below had no basis for considering the application of the statute to negligent or inadvertent conduct. In sum, section

409.920(2)(e) in no way stands as an obstacle to the accomplishment of federal purposes and objectives, and therefore the <u>mens rea</u> requirements in 42 U.S.C. § 1320a-7b(b) and the safe harbor provision do not preempt Florida law. Moreover, defendants did not prove the existence of a bona fide employment relationship, and their drivers' solicitations and referrals were not a "covered item or service" that would allow them to claim the benefit of the safe harbor provision. Accordingly, the lower courts erred as a matter of law in holding section 409.920(2)(e) preempted.

II. THE SAFE HARBOR STATUTE DOES NOT PROTECT HARDEN'S "PER-HEAD" PAYMENT SCHEME FOR SOLICITATION AND REFERRAL OF ELIGIBLE MEDICAID PATIENTS.

The safe harbor statute simply does not shelter the type of referral payment made here, even if made to a bona fide employee. Such payment is a prohibited kickback under the federal law.

In rejecting the State's arguments on this point, the trial court relied heavily on its interpretation of the decision in <u>United States ex rel. Obert-Hong v. Advocate</u> <u>Health Care</u>, 211 F. Supp. 2d 1045 (N.D. Ill. 2002). The trial court entirely misconstrued this decision. It is completely consistent with <u>United States v. Starks</u> and fatal to defendants. Not surprisingly, the Third District did not even mention <u>Obert-Hong</u>.

In <u>Obert-Hong</u>, a hospital network acquired the medical practices of various physicians and then signed them to employment contracts which the federal district court considered bona fide employment relationships under the safe harbor statute. The critical issue was the nature and purpose of the physicians' remuneration. With respect to the federal district court's analysis, the trial court here stated:

The opinion makes clear that the amounts paid to the doctors under the employment aspect of the contracts were expressly based on "a percentage of fees collected for referred patients." <u>Obert-Hong</u>, 211 F. Supp. at 1047. That is the doctors were paid on a commission basis, similar to the manner in which Harden paid the drivers in this case.

R1: 180-181. (footnote omitted).

However, in the above quotation from the <u>Obert-Hong</u> decision, the federal district court was merely paraphrasing the relator's allegations. It most certainly did not approve compensating employees on a "per-head" basis for referrals. What the district court actually concluded was this:

The [contract] provisions in question state that the doctor shall receive a percentage of receipts <u>for professional</u> <u>services</u>. In some cases the percentage differs, depending on whether the services are provided in the hospital or the doctor's office. <u>But both depend on the value of work</u>

performed by the individual doctor, not the value of any referrals.

211 F. Supp. 2d at 1050 (emphasis added). The district court considered both the safe harbor employee exception and the Stark Act finding the percentage compensation for the physicians was based on professional services and was independent of referrals. <u>Id.</u> at 1051. Therefore, there was no economic inducement to refer patients. <u>Id.</u>

Defendant's payment scheme is completely different. First, the drivers did not provide covered professional services and are not compensated for such services. <u>Obert-Hong</u> is thus consistent with <u>Starks</u>: the employee must provide a covered service or item. The drivers' solicitations and referrals are not such a service or item. Moreover, as the <u>Obert-Hong</u> court reasoned, the federal Anti-Kickback statute is "designed to remove economic incentives from medical referrals." <u>Id.</u> at 1050. Employee compensation is therefore not exempt under the safe harbor provision when "directly related to referrals." <u>Id.</u> Here, the drivers' compensation is *directly related* to referrals and they had every economic incentive to refer patients to Dental Express. They were not paid for anything else. The compensation was not for professional services, but was based strictly on referrals.

The trial court suggested the State's reliance on <u>Obert-Hong</u> was misplaced because the federal district court was construing the Stark act, not the Anti-Kickback statute and safe harbor provision. R1: 181-182. That is simply not the case. The federal district court addressed both statutes and found neither permitted compensation for referrals.

Moreover, under the federal Anti-Kickback statute, it is beyond dispute a Medicaid provider could not pay a third party to refer a patient, anymore than it could pay a kickback to a patient. See United States v. Polin, 194 F.3d 863 (7th Cir. 1999). In fact, at least four federal circuits have adopted the "one purpose" test, which holds the Anti-Kickback statute is violated if one purpose of a payment is to induce referrals, even though the payment may arguably compensate for some service. <u>United States</u> v. McClatchey, 217 F.3d 823, 834-835 (10th Cir. 2000)(citing cases). See also United States v. LaHue, 261 F.3d 993, 1003-1004 (10th Cir. 2001) (same). Yet the decision of the trial court would allow a Medicaid physician's employee to receive a "per-head" kickback for every patient recruited, thus creating the exception that swallows the rule. The Third District's decision did not approve this interpretation but simply tried to twist the predicate by asserting the defendants were paying "transportation" costs, not kickbacks for referrals. But as defendants admitted, they were paying \$25 in cash for every eligible patient referred. R2:217-218 (transcript); SR1:1 ¶ 5e.

The Third District's attempt to recast the issue fails for the reasons discussed in part I.C., <u>supra</u>. Accordingly, because the Dental Express drivers are not employees and do not provide professional (and covered) services, they are not entitled to claim protection under the safe harbor provision. But even if they were, the case law makes clear kickbacks to employees for referrals are not protected.

III. THE TRIAL COURT'S OTHER GROUNDS FOR INVALIDATING SECTION 409.920(2)(e) ARE MERITLESS.

The district court did not address the trial court's other grounds for invalidating section 409.920(2)(e). In the event this Court finds it necessary to reach those grounds, they are addressed briefly.

A. Section 409.920(2)(e) Does Not Violate The First Amendment.

1. Section 409.920(2)(e) does not inhibit First Amendment rights.

Relying on <u>State v. Bradford</u>, 787 So. 2d 811 (Fla. 2001), the trial court held "a Medicaid provider's 'solicitation' of patients, at least those solicitations made by its own employees" is protected by the First Amendment." R 1:186. Because the trial court found that section 409.920(2)(e) violated the First Amendment's "narrowly tailored" test, it concluded the statute was unconstitutional. R 1:187. Unlike the situation in <u>Bradford</u>, this case does not involve an inhibition on the defendants' right generally to solicit business. Section 409.920(2)(e) merely prohibits solicitation and referrals in direct return for payment. This prohibition is narrowly tailored to achieve the legislature's objective of prohibiting kickbacks for patient referrals. It clearly does not prohibit routine advertising and marketing.

The question of whether the federal Anti-Kickback statute implicates constitutional rights has come before courts at least three times. Addressing vagueness challenges, each of these courts found the federal Anti-Kickback statute regulates only economic conduct and does not chill constitutional rights. <u>United States v. Starks</u>, 157 F.3d 833, 839-840 (11th Cir. 1998); <u>United States v. LaHue</u>, 261 F.3d 993, 1005 (10th Cir. 2001); <u>Hanlester Network v. Shalala</u>, 51 F.3d 1390, 1398 (9th Cir. 1995).

These cases make clear the anti-kickback statutes do not implicate constitutional rights because they merely impose conditions to doing business with the State.

2. The defendants' employer waived its First Amendment right to solicit Medicaid clients.

Even if the anti-kickback statute did implicate a First Amendment right of the defendants, any such right was waived. The law requires Medicaid providers to waive any First Amendment "right" of its employees to solicit Medicaid clients on its behalf. Federal and state law require every Medicaid provider to consent to a "provider agreement" as a condition for receiving Medicaid funds. 42 U.S.C. § 1396a(a)(27); § 409.907(1),(2), Fla. Stat.; <u>Agency for Health Care Admin. v. Baker County Medical Servs. Inc.</u>, 832 So. 2d 841 (Fla. 1st DCA 2002) (action for breach of Medicaid provider agreement). The provider agreement "shall require the provider to comply fully with all state and federal laws pertaining to the Medicaid program." § 409.907(1), Fla. Stat. Such agreement "shall be a **voluntary** contract between the agency and the provider, in which the provider agrees to comply with all laws and rules pertaining to the Medicaid program when furnishing a service or goods to a Medicaid recipient." § 409.907(2), Fla. Stat. (emphasis added).

One such "law pertaining to the Medicaid program" the provider implicitly agreed to comply with, of course, was the state anti-kickback statute, section 409.920(2)(e). Thus, by entering the provider agreement, Dental Express waived any arguable "right" to pay kickbacks for solicitation and referrals.

Waivers of constitutional rights are perfectly permissible. <u>See</u>, <u>e.g.</u>, <u>Gillman v.</u> <u>Butzloff</u>, 22 So. 2d 263, 265 (Fla. 1945). The test for gauging the validity of a waiver of constitutional rights is whether it was knowing, voluntary, and intelligent. <u>D.H.</u> <u>Overmeyer Co., Inc. of Ohio v. Frick Co.</u>, 405 U.S. 174, 185 (1972). First Amendment rights to solicit business are among those which can be waived. <u>Paragould</u> <u>Cablevision Inc. v. City of Paragould, Arkansas</u>, 930 F.2d 1310 (8th Cir. 1991).

Because Florida law mandates Medicaid provider agreements are voluntary and that they contain an acquiescence to the laws governing the Medicaid program, any First Amendment "right" to pay for solicitation and referral of Medicaid patients was waived as a matter of law.

B. The Statute Is Not Void For Vagueness.

The trial court held the term "unlawful remuneration" in section 409.920(2)(e) is unconstitutionally vague under the due process clauses of the federal and state constitutions. R 1:188-89. The trial court said the "term 'unlawful remuneration' is vague because it does not give a Medicaid provider fair 'notice' that paying even its own employees to 'solicit' business is (allegedly) unlawful." R 1:188.

The trial court misread the statute. It does not contain the term "unlawful remuneration." Instead, the operative portion of section 409.920(2)(e) uses the term "any remuneration":

Knowingly solicit, offer, pay, or receive **any remuneration**, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual . . .

(Emphasis added). The term "any remuneration" is obviously different than "unlawful remuneration." The trial court held the statute unconstitutionally vague based on non-existent language.

The test for vagueness is whether the language of the statute provides adequate notice of the conduct prohibited "when measured by common understanding and practice." <u>State v. Brake</u>, 796 So. 2d 522, 528 (Fla. 2001). The statute's language must provide a "definite warning of what conduct is required or prohibited" with sufficient specificity that it does not encourage arbitrary and discriminatory enforcement. <u>Id.</u> at 528-29. <u>See also State v. Riker</u>, 376 So. 2d 861 (Fla. 1979).

There is nothing vague about the term "any remuneration" as used in this statute. "Any" in this context means "all." <u>Webster's Ninth New Collegiate Dictionary</u> (1983), p. 93. "Remuneration" means a payment for a service. <u>Id.</u> at 997. Thus, **all payments** "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program" are illegal. This is clear enough for any reasonable person to understand.

The defendants are charged with precisely this violation: paying people in exchange for the referral of Medicaid patients. A person charged with behavior clearly

prohibited by the act lacks standing to mount a vagueness challenge. <u>United States v.</u> <u>LaHue</u>, 261 F.3d 993, 1006 (10th Cir. 2001).

The trial court apparently confused state law and federal law. The term "illegal remuneration" appears in the federal anti-kickback statute. 42 U.S.C. § 1320a-7b(b). "Illegal remuneration" is defined as "whoever knowingly and willfully solicits <u>any</u> remuneration. . . ." <u>Id.</u> (emphasis added). Federal courts have upheld this provision against vagueness challenges. <u>See United States v. LaHue</u>, 261 F.3d 993, 1005 (10th Cir. 2001); <u>United States v. Neufeld</u>, 908 F.Supp. 491, 495 (S.D. Ohio).

The trial court erred in finding the statute void for vagueness based upon a phrase that it does not contain, and a phrase which has withstood vagueness challenges in federal courts.

CONCLUSION

For the foregoing reasons, the State respectfully requests the Court reverse the

decision below and remand for further proceedings against the defendants.

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 June, 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 PlazaSuite 700Miami, FL 33131*Counsel for G. Harden*

STEVEN BUSTAMANTE

8500 SW 92nd Street Suite 202 Miami, FL 33156 *Counsel for E. Polsky*

MICHAEL BAND

2601 S. Bayshore Drive Suite 1600 Miami, FL 33133 *Counsel for M. Rodriguez*

AUBREY RUDD

7901 SW 67th Avenue Suite 206 Miami, FL 33143 *Counsel for H. Goss*

CARLOS GONZALEZ

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

G. RICHARD STRAFER, P.A.

2400 South Dixie Highway Suite 200 Miami, Florida 33133 *Attorney for Appellee, Gabriel Harden*

ROBERT COLUMBE, Esq.

19 West Flagler Street, Ste 720 Miami, FL 33130 Attorney for Appellee Flora Johnson

ANNETTE GOMEZ, Esq.

644 N.W. 17th Avenue Miami, FL 33125 *Attorney for Appellee Bruce Eric Smith*

MARK SHUMAKER, Esq.

640 N.W. 15th Avenue Boca Raton, FL 33486 Attorney for Appellee 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.

CHRISTOPHER M. KISE

CERTIFICATE OF COMPLIANCE

I hereby certify that the State of Florida's Initial Brief complies with the font requirements of Fla. R. App. P. 9.210(a)(2), in that this Brief uses Times New Roman 14-point font.

CHRISTOPHER M. KISE