IN THE SUPREME COURT OF FLORIDA

STATE OF FLORIDA,

Plaintiff/Appellant

v.

Case No. SC04-613
L.T. Case No. 3D03-521

GABRIEL HARDEN, et al.

Defendants/Appellees
_______________________________________/

AMENDED BRIEF OF SONNENSCHEIN NATH & ROSENTHAL LLP
AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES

Filed By Consent of the Parties

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TABLE OF CONTENTS

TABLE OF CONTENTS..i

TABLE OF AUTHORITIES……………………………………………………….iii

STATEMENT OF INTEREST……………...…………………………………...1

STATEMENT OF THE CASE…………………………………………………..2

SUMMARY OF THE ARGUMENT………………………...…………………2

BACKGROUND ………………………..……………………………………..3

1. The Medicaid Program…………………………………………………3

2. The Federal Health Care Program Anti-Kickback Law……………………..4

   A. Elements of a Federal Anti-Kickback Law Violation…..……………….4

   B. History and Development of the Federal Anti-Kickback Law……….4

   C. The Federal Regulatory Safe Harbors…………………………….…6

3. The Florida Medicaid Anti-Kickback Law…………………………………7

4. Consequences of Conviction Under the Florida Medicaid Anti-Kickback Law…………………………………………………………..……………8

ARGUMENT…………………………………………………………………...8

1. The Florida Medicaid Anti-Kickback Law is Preempted Because It Directly Conflicts with the Federal Anti-Kickback Law……..……………….9

   A. The Scope and Structure of the State and Federal Statutes Differ Dramatically……..…………………………………………….....9

   B. The Florida Medicaid Anti-Kickback Law Stands as an

Obstacle to the Purposes and Objectives of Congress……………....11

C. The Florida Medicaid Anti-Kickback Law Conflicts with the Federal Anti-Kickback Law Because It Prohibits Many Payments to Bona Fide Employees…….……………………..13

D. The Florida Medicaid Anti-Kickback Law, Prior to Recent Legislative Amendment, Conflicted with the Federal Anti-Kickback Law Because It Criminalized Inadvertent Conduct.……………………………..…17

E. HHS-OIG's Statements Regarding Preemption Do Not Relate to the Type of Implied Conflict Preemption Presented Here………..19

F. The Presumption Against Preemption Does Not Apply to the Florida Medicaid Anti-Kickback Law…………………………...20

CONCLUSION……………………………………………………………..20

CERTIFICATE OF TYPE SIZE AND STYLE……………………………….22

TABLE OF AUTHORITIES

CASES

Barnett Bank of Marion County v. Nelson, 517 U.S. 25 (1996)............................11

Bryan v. United States, 524 U.S. 184 (1998)..17

Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984)...............14

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)...9

Felder v. Casey, 487 U.S. 131 (1988)...9

Gade v. National Solid Wastes Mgmt. Ass'n., 505 U.S. 88 (1992)....................9, 11

Harris v. McRae, 448 U.S. 297, 301 (1980)...20

Muratore v. United States OPM, 222 F.3d 918 (11th Cir. 2000)...........................19

Pharmaceutical Research and Mfr. of Am. v. Meadows, 304 F.3d 1197 (11th Cir. 2002)...3

The Public Health Trust of Dade Co. v. Jackson Memorial Hospital, 693 50 2d 562, 564 (Fla. 3rd DCA 1996)..20

U.S. ex rel. Obert-Hong v. Advocate Health Care, 211 F.Supp. 2d 1045 (N.D. Ill. 2002)...13, 16

United States v. Jain, 93 F.3d 436 (8th Cir. 1996)..5

United States v. Starks, 157 F.3d 833 (11th Cir. 1998)....................................14, 18

United States v. Tapert, 625 F.2d 111 (6th Cir. 1980)...4

OTHER AUTHORITIES

42 U.S.C. § 1320a-7..8

42 U.S.C. § 1320a-7b..1, 3, 4, 5, 11, 12, 13, 17

42 U.S.C. § 1320a-7d(a)(1)(A)...6

42 U.S.C. §§ 1396 *et seq*...2

42 U.S.C. § 1396a(a)(25)...16

42 U.S.C. § 1396b...3

42 C.F.R. § 449.15...16

42 C.F.R. § 433.138...16

42 C.F.R. § 433.139(d)..16

42 C.F.R. § 433.159...16

54 Fed. Reg. 3088 (Jan. 23, 1989)..6

56 Fed. Reg. 35952 (July 29, 1991)...6, 14, 19

68 Fed. Reg. 23731 (May 5, 2003)...15

HHS-OIG Advisory Opinion 04-09 (July 15, 2004)..15

Omnibus Reconciliation Act of 1980, P.L. 96-499, § 917, 94 Stat. 2599 (1980).....5

Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93, § 14(a), 101 Stat. 697 (1987)..5

P.L. 89-97, 79 Stat. 344 (1965)...4

H.R. Rep. No. 95-293 (II), 95th Cong., 1st Sess., at 53, reprinted in (1977) U.S.C.C.A.N. 3039, 3055..4, 11

H.R. Rep. No. 1167, 96th Cong., 2d Sess., at 59 (1980), reprinted in 1980 U.S.C.C.A.N 5562, 5572...5, 18

OIG Special Advisory Bulletin, Effect of Exclusion from Federal Health Care Programs (1999)..8

Fla. Stat. § 409.920..1, 7, 8, 13, 18

Fla. Stat. § 409.908(12)(b)..16

Fla. Stat. § 456.054..20

Fla. Stat. § 817.505..20

Florida Senate Staff Analysis and Economic Impact Statement - SB 1064............18

Tex. Occ. Code §§ 102.001, *et seq*..12

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STATEMENT OF INTEREST

Sonnenschein Nath & Rosenthal LLP ("SNR") is a full-service, national law firm. Our clients include a wide variety of entities that play a crucial role in the delivery of health care in the United States, such as hospitals, physicians, pharmaceutical and device manufacturers, durable medical equipment suppliers, group purchasing organizations, and managed care plans. We counsel our clients concerning compliance with anti-kickback, false claims, physician self-referral and other federal and state health care program requirements.

Many of our clients provide services and supplies in the State of Florida. By virtue of its incongruence with its federal counterpart, the Florida Medicaid Anti-Kickback Law (the "Florida Medicaid AKL") directly affects these clients' businesses. As such, the determination whether the Florida Medicaid AKL is constitutional is of great interest to them, especially one that is currently under investigation by the State of Florida Office of Attorney General Medicaid Fraud Control Unit for alleged violation of the Florida Medicaid AKL.

SNR presents this brief as an *Amicus Curiae* with the consent of the State of Florida and the remaining parties to this case. As such, SNR presents no Statement of Facts and has focused on the questions of law within SNR's knowledge and interest. SNR urges the court to uphold the decision of the Florida Third District Court of Appeals for the reasons set forth below.

STATEMENT OF THE CASE

This case involves a challenge to the constitutionality of the anti-kickback law provisions of the Florida Medicaid AKL, Fla. Stat. Ann. § 409.920(2) (2002), on the grounds that these provisions: (1) are preempted by the federal health care program anti-kickback law, 42 U.S.C. § 1320a-7b(b) (the "Federal AKL"); (2) are unconstitutionally vague; and (3) violate the First Amendment to the United States Constitution. The Eleventh Judicial Circuit Court for Miami-Dade County held that the Florida Medicaid AKL is unconstitutional for the reasons set forth above. The Third District Court of Appeals affirmed the Circuit Court's holding.[1]

Amicus Curiae files this brief in support of Appellees, having filed a similar brief with the District Court. *Amicus Curiae* addresses the preemption issue only — i.e., whether the Florida Medicaid AKL stands as an obstacle to the purpose and objectives of, and is therefore preempted by, the Federal AKL.

SUMMARY OF THE ARGUMENT

The Medicaid program is a federal health care program and is expressly covered by and subject to the Federal AKL. See 42 U.S.C. § 1320a-7b(f). Recognizing that the Federal AKL is a sweeping criminal statute, Congress enacted statutory exceptions and mandated that the U. S. Department of Health and Human Services ("HHS") promulgate regulatory safe harbors that protect and

[1] The District Court considered the preemption issue dispositive and did not address the vagueness and First Amendment issues.

encourage certain beneficial financial arrangements (e.g., employee compensation and price reductions on items and services). Although equally sweeping in reach, the Florida Medicaid AKL does not include any exceptions or safe harbors. Thus, the Florida statute criminalizes the very conduct that, with respect to the Medicaid program, Congress has affirmatively and expressly protected.

Because enforcement of the Florida Medicaid AKL directly conflicts with, and indeed frustrates, Congress' purpose regarding the Medicaid program, the Florida Medicaid AKL is preempted pursuant to Article VI, Clause 2, of the United States Constitution (the "Supremacy Clause").

BACKGROUND

1. The Medicaid Program

Congress established the Medicaid program in Title XIX to the Social Security Act of 1965 ("SSA") to provide medical assistance to low income families and individuals. 42 U.S.C. §§ 1396 *et seq.* In a nutshell, Title XIX (1) authorizes the federal government to make participation payments to states that meet certain federal program requirements and (2) authorizes states to use federal funds to provide medical assistance to individuals who satisfy federal eligibility criteria. Id. Although states administer the Medicaid program, "the cooperative venture between the federal and state governments is governed by the terms of Title XIX." Pharmaceutical Research and Mfr. of Am. v. Meadows, 304 F.3d 1197, 1200 (11th Cir. 2002). Furthermore, to avoid any confusion as to the

Federal AKL's reach and intent, Congress included Medicaid as a "Federal health care program" governed by the statute. See 42 U.S.C. § 1320a-7b(f).

2. The Federal Health Care Program AKL

. Elements of a Federal AKL Violation

It is illegal knowingly and willfully to offer or pay remuneration — directly or indirectly, overtly or covertly, in cash or in kind — to induce another person to (1) refer an individual for the furnishing (or arranging for the furnishing) of any item or service for which payment may be made under a federal health care program; (2) purchase, lease or order such items or services; or (3) arrange for or recommend the purchase, lease or order of such items or services. 42 U.S.C. § 1320a-7b(b)(2). The Federal AKL also prohibits the solicitation or receipt of remuneration in exchange for such conduct. See id. § 1320a-7b(b)(1).

. History and Development of the Federal AKL

Congress enacted the Federal AKL as part of the 1972 SSA amendments. Originally, the statute prohibited Medicaid program participants from soliciting, offering or receiving kickbacks, bribes or rebates for referring individuals for items or services payable by Medicaid. See P.L. 89-97, 79 Stat. 344 (1965).

In 1977, Congress stengthened the Federal AKL. See H.R. Rep. No. 95-293(II), 95th Cong., 1st Sess., at 53 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3055. It replaced the narrow terms "kickbacks," "bribes," and "rebates" in the original statute with the far more sweeping term "remuneration," thereby

subjecting a much broader range of conduct — including commercially legitimate and beneficial transactions — to potential criminal prosecution. See United States v. Tapert, 625 F.2d 111, 113 nn.1-2 (6th Cir. 1980) (discussing the change in statutory language effectuated by the 1977 amendments).

Recognizing the potential for criminalizing appropriate arrangements, Congress initially addressed the expanded scope of the Federal AKL by exempting two common financial arrangements: (1) properly disclosed discounts or other price reductions and (2) payments to bona fide employees. See 42 U.S.C. 1320a-7b(b)(3)(A) and (B). Thereafter, Congress adopted additional statutory exceptions, including payment practices identified in regulatory safe harbors. 42 U.S.C. § 1320a-7b(b)(3)(C), (D) - (F).

In 1980, Congress further narrowed the reach of the Federal AKL by requiring that violations be knowing and willful. See Omnibus Reconciliation Act of 1980, P.L. 96-499, § 917, 94 Stat. 2599, 2625 (1980). The addition of this heightened *mens rea* standard reflected Congressional concern "that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 1167, 96th Cong., 2d Sess., at 59 (1980), reprinted in 1980 U.S.C.C.A.N. 5562, 5572. See also, United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996).

Concerned with the breadth of the Federal AKL, in 1987 Congress mandated that HHS publish safe harbor regulations to protect and promote fundamentally

beneficial arrangements. See Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93, § 14(a), 101 Stat. 697 (1987). Arrangements that meet the requirements of these safe harbors are immunized under the Federal AKL.[2] See 42 U.S.C. § 1320a-7b(b)(3)(E).

. The Federal Regulatory Safe Harbors

Pursuant to rulemaking authority delegated by the HHS Secretary, the HHS Office of Inspector General ("HHS-OIG") promulgated regulatory safe harbors to protect payment practices "potentially capable of inducing referrals of business." 56 Fed. Reg. 35952 (July 29, 1991). In proposing its first set of safe harbors, HHS-OIG noted that the Federal AKL "is extremely broad" and that the safe harbors were designed to allay concern "that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution." 54 Fed. Reg. 3088 (Jan. 23, 1989).

In total, these safe harbors address 22 common business or payment practices that implicate (and, at least technically, violate) the Federal AKL, but have been deemed to be sufficiently beneficial or innocuous so as to be permitted, if not encouraged. Thus, while the language of the Federal AKL remains broad, its

[2] In 1996, Congress took two additional steps to protect conduct beneficial to federal health care programs: (1) it directed HHS to implement an advisory opinion process by which private parties could request clarification of the application of the Federal AKL and its penalties to a particular set of facts; and (2) it directed HHS to solicit and consider proposals for new safe harbors annually. See 42 U.S.C. § 1320a-7d(a)(1)(A).

reach has been significantly and carefully tailored by Congress through the six statutory exceptions, 22 separate safe harbors, and the heightened *mens rea* requirement. In Congress' view, absent such narrowing, enforcement of the Federal AKL would seriously discourage health care companies and providers from meaningfully participating in the Medicare and Medicaid programs and, as such, would give rise to patient access concerns.

3. **The Florida Medicaid AKL**

The Florida Medicaid AKL closely mirrors the Federal AKL. Lifting large portions of the Federal AKL, the Florida Medicaid AKL makes it a felony for any person to:

> 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.

Fla. Stat. § 409.920(2)(e).

In stark contrast to the federal statute, however, the Florida Medicaid AKL does not include any exceptions — or authorize administratively promulgated safe harbors — to protect beneficial or non-abusive arrangements and practices.

4. Consequences of Conviction Under the Florida Medicaid AKL

A conviction under the Florida Medicaid AKL has serious collateral consequences apart from potential criminal fines and incarceration. Pursuant to 42 U.S.C. § 1320a-7(a)(1), a person convicted of a Medicaid offense related to any federal health care program is excluded from participating in (i.e., receiving payment from) all federal health care programs.[3] This administrative sanction, commonly referred to as HHS-OIG's "mandatory exclusion authority," is tantamount to a death knell for healthcare providers or individuals who furnish Medicare, Medicaid, or other federal health care program services.

ARGUMENT

1. The Florida Medicaid AKL is Preempted Because It Directly Conflicts with the Federal AKL.

It is well-settled that a state law that conflicts with federal law is "without effect." See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). Even where federal law does not expressly preempt state law, preemption may be implicit if state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Gade v. National Solid Wastes Mgmt. Ass'n., 505 U.S. 88, 98 (1992) (quotations and citations omitted); see also Felder v. Casey, 487 U.S. 131, 138 (1988). Thus, the "ultimate task in any

[3] "[T]he most significant Federal health care programs are Medicare, Medicaid, Tricare and the Veterans programs." OIG Special Advisory Bulletin, Effect of Exclusion from Federal Health Care Programs, at n.1 (1999), available on the OIG website at http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm#N_1_.

preemption case is to determine whether state regulation is consistent with the structure and purpose of the [federal] statute as a whole." Gade, 505 U.S. at 98. In this case, the sweeping, unfettered nature of the Florida Medicaid AKL conflicts with the structure and purpose of the Federal AKL because the state law prohibits — indeed criminalizes — a broad range of common commercial relationships involving Medicaid that Congress has explicitly and specifically protected.

. The Scope and the Structure of the State and Federal Statutes Differ Dramatically.

In its District Court brief, Appellant argued that the Florida Medicaid AKL and the Federal AKL were consistent by isolating individual provisions of each and characterizing the differences as minor or unimportant. See D. Ct. App. Br. at 22. In contrast, Appellant now encourages this Court to view the laws "as a whole" and argues that preemption is not warranted in this case because the Florida Medicaid AKL and Federal AKL exist within a complimentary framework in pursuit of common purposes. See App. Br. at 14. Whether seeking to characterize the differences between the two laws as insignificant or viewing their collective structure and purpose "as a whole," Appellant's position fails. At bottom, the two laws are vastly different and fundamentally irreconcilable.

Structurally, the Federal AKL establishes a broad prohibition on the transfer of remuneration for referrals, but then appropriately provides for statutory exceptions and regulatory safe harbors. The purpose and effect of the Federal

AKL is to prohibit fraudulent and abusive transfers while concurrently protecting (through exceptions and safe harbors) those arrangements that while technically covered by the prohibition are commercially beneficial and non-abusive. In contrast, the Florida Medicaid AKL contains sweeping prohibitions with no exceptions. Thus, when viewed as a whole, the Federal AKL protects a broad array of conduct that the Florida Medicaid AKL criminalizes.

. The Florida Medicaid AKL Stands as an Obstacle to the Purposes and Objectives of Congress.

Appellant argues that the Florida Medicaid AKL does not stand as an obstacle to the Federal AKL because it is "possible" for a Medicaid provider to comply with both laws. Furthermore, Appellant postulates that merely because the Florida Medicaid AKL is more stringent than the Federal AKL does not make it impossible for a provider to comply with both. See App. Br. at 16.

However, the test for preemption is whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Gade, 505 U.S. at 98. The Florida Medicaid AKL criminalizes activity that the Federal AKL protects and thus, the Florida Medicaid AKL clearly stands as an obstacle to the purposes and objectives of Congress. See e.g., Barnett Bank of Marion County v. Nelson, 517 U.S. 25, 31 (1996) ("[T]he Federal Statute authorizes national banks to engage in activities that the State Statute expressly

forbids. Thus, the State's prohibition of those activities would seem to 'stand as an obstacle to the accomplishment' of one of the Federal Statute's purposes….")

When amending the Federal AKL, Congress intentionally defined the term "remuneration" to encompass the widest possible range of potentially abusive activities. See H. Rep. No. 95-293(II), at 53 (1977). Recognizing that such a broad prohibition would capture commercially beneficial activities, Congress included statutory exceptions to ensure that "normal course of business transactions would not be deemed illegal." Id. For example, Congress protected certain discounts and other price reductions. Id.; see also 42 U.S.C. § 1320a-7b(b)(3)(A). Congress included this statutory exception to ensure that discounting — considered by Congress "a good business practice which results in savings to [M]edicare and [M]edicaid program costs — would remain legal," and to affirmatively "encourage providers to seek discounts." Id.

Florida's Medicaid AKL defeats this Congressional purpose because, unlike its federal counterpart, Florida's unchecked statutory prohibition on the payment, offer or receipt of remuneration makes no exception for discounts or other price reductions. The following hypothetical demonstrates this untenable conflict:

> A distributor of medical supplies sells a walking cane for a list price of $20. A Florida hospital and Texas hospital engage the distributor in separate negotiations for the purchase of canes. The distributor proposes to sell the canes at a discount of $2 per cane — to be paid in the form of quarterly rebates — in order to induce the hospitals to order or purchase the item from the distributor rather than a competing distributor. To avoid

> violating the Federal AKL, however, the parties to the transaction — the seller and the buyers — take appropriate steps to disclose and reflect the discount (rebate) pursuant to the requirements of the statutory exception and regulatory safe harbor for discounts.

In this hypothetical, the Texas hospital (and concomitantly Medicare and the Texas Medicaid program) are able to take advantage of, and benefit from, the price reduction because the remuneration at issue — i.e., the $2 per cane rebate — is protected from prosecution both under the Federal AKL and its Texas counterpart, which incorporates by reference the exceptions and safe harbors of the federal law. See Tex. Occ. Code §§ 102.001, *et seq*. ("[the Texas Anti-Kickback Law] permits any payment, business arrangement, or payment practice permitted by [the Federal AKL] or any regulation adopted under the law").

The Florida hospital, by contrast, is prohibited from proceeding with the transaction, notwithstanding the federal mandate to the contrary, because the Florida AKL criminalizes the knowing receipt of "any remuneration including . . . any rebate . . . in return for . . . purchasing, leasing, ordering . . . any goods . . . item, or service, for which payment may be made . . . under the Medicaid program." Fla. Stat. 409.920(2). The distributor also faces criminal conviction — and exclusion from Medicare and Medicaid — despite acting in accordance with Congressional purpose and intent.

Thus, application of the Florida law to this common discounting practice clearly defeats the Congressional intent to encourage price discounts and promote

cost savings to the Medicaid program, and ultimately the taxpayers. As such, Florida's Medicaid AKL unquestionably stands as a direct obstacle to the full purpose and objectives of Congress and compliance with both laws is impossible.

. The Florida Medicaid AKL Conflicts with the Federal AKL Because It Prohibits Many Payments to Bona Fide Employees.

The Federal AKL expressly protects amounts paid by an employer to a bona fide employee engaged in the provision of covered items or services. See 42 U.S.C. § 1320a-7b(b)(3)(B); see also U.S. ex rel. Obert-Hong v. Advocate Health Care, 211 F.Supp. 2d 1045, 1048 (N.D. Ill. 2002). According to HHS-OIG, this protection extends to commission-based payments made to part-time employees, as well as to payments not only for the provision of medical care, but also for soliciting business. See 56 Fed. Reg. 35952, 35981 (July 29, 1991). More specifically, HHS-OIG has explained that the employee safe harbor permits "an employer to pay an employee in whatever manner he or she [chooses] for having [an] employee assist in the solicitation of program business."[4]

In contrast, Appellant argues that the Federal AKL employee exception and safe harbor only protect arrangements under which an employee actually furnishes a covered medical item or service. In support of this contention, Appellant cites dicta in United States v. Starks (157 F.3d 833 (11th Cir. 1998)) that employees who

[4] 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989); see also 56 Fed. Reg. at 35953. This reasonable interpretation of the employee exception by the agency responsible for administering the statute is entitled to considerable deference. See Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837, 844-45 (1984).

are not paid for furnishing any covered service may not "claim the protection of the safe harbor provision as employees." See App. Br. at 21. The dicta in Starks is entirely distinguishable because the Starks court was writing in the context of hidden and illicit payments made to employees of another company (not the payor) in parking lots. Moreover, this argument is contrary to the plain language of the safe harbor, Congressional intent, and the operation of the Medicaid payment system. Finally, in the 13 years since the promulgation of the employee safe harbor, HHS-OIG has never made the distinction being advocated by Appellant.

As noted on page 32 of Appellees' brief, under the employee safe harbor, employees may be employed in the "furnishing" of covered items or services by assisting with a health care provider's operations. HHS-OIG has clearly stated that protection under the employee safe harbor is not premised on an employee directly furnishing clinical care items (payments by pharmaceutical companies to employed sales representatives who solicit additional business from physicians in the form of drug sales are protected). See HHS-OIG CPG for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23739 (May 5, 2003). A recent HHS-OIG advisory opinion applying the Federal AKL also illustrates that to be protected under the employee safe harbor, an employee need not perform the actual covered service. See HHS-OIG Advisory Opinion 04-09 at pg. 4 (July 15, 2004).[5]

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[5] The Advisory Opinion is available at (http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0409.pdf.).

Furthermore, under the Florida Medicaid dental payment system (a fee schedule), payments are made based on the covered item or service. For example, Medicaid pays $72.00 for sealing a tooth. See Medicaid Dental Services Fee Schedule.[6] This $72.00 fee constitutes payment in full not only for the actual furnishing of the medical procedure, but also all other expenses associated with the dentist's performance of the procedures such as the dentist's overhead costs — e.g., rent, receptionist salary, equipment purchase/rental, and marketing expenses.[7] There are no separate payments for these services furnished by the "back-office" staff, all of which are necessary to enable the dentist to perform the medical procedure. See Fla. Stat. § 409.908(12)(b).

Appellant also attempts to argue that any payments tied to referrals whether made to employees or non-employees, violate both the Florida Medicaid AKL and the Federal AKL. In support of this contention, Appellant cites Advocate Health Care. However, Appellant misreads the Advocate Health Care decision, which indicates that "all" compensation paid to an employee is protected by the Federal AKL. Advocate Health Care, 211 F.Supp.2d. at 1051.

Finally, Appellant mistakenly relies on the "one purpose test," which as applied by HHS-OIG holds that the Federal AKL is violated if one purpose of a

[6] The Medicaid Dental Fee Schedule, effective 01/01/04, is available at http://floridamedicaid.consultec-inc.com/index.jsp?display=fees.
[7] Medicaid providers are required to consider Medicaid payments as "payment in full" for all services administered through the program. 42 U.S.C. § 1396a(a)(25); 42 C.F.R. § 449.15, 42 C.F.R. §§ 433.138, 433.139(d), and 433.159.

payment is to induce referrals, even though the payment may arguably compensate for some other purpose. See App. Br. at 30. What Appellant fails to acknowledge about the "one purpose test" is that it only applies in those situations where the activity is not protected by a safe harbor. An arrangement that complies with the requirements of a safe harbor, regardless of the intent of the parties to the arrangement, is protected from Federal AKL scrutiny. As such, an employer may intend to and actually pay a bona fide employee to solicit referrals.

Because the Florida Medicaid AKL unequivocally prohibits any employer from paying its bona fide employee to generate business by soliciting patients, ordering items or services, or the like, it materially conflicts with the Federal AKL and the underlying Congressional purpose and objectives to protect all payments between employers and employees for the furnishing of covered items or services. Thus, preemption is not only warranted but required.

. The Florida Medicaid AKL, Prior to Recent Legislative Amendment, Conflicted with the Federal AKL Because It Criminalized Inadvertent Conduct.

Violation of the Federal AKL must be both knowing and willful. 42 U.S.C. § 1320a-7b(b)(2). Knowledge and willfulness are distinct standards. To establish a "knowing" violation, the government must prove that the defendant had "knowledge of the facts that constitute the offense;" "to establish a 'willful' violation of a statute, the [g]overnment must prove that the defendant acted with knowledge that his conduct was unlawful." Bryan v. United States, 524 U.S. 184,

191-93 (1998) (quotations and citations omitted). Federal AKL culpability attaches only in cases where a defendant engages in conduct with knowledge of the factual circumstances and actual knowledge that the conduct was wrongful or illegal. See Starks, 157 F.3d at 838.

Congress added the "knowingly and willfully" requirement to the Federal AKL to avoid the application of "criminal penalties . . . to an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 96-1167, at 59 (1980).

Until July 1, 2004, the Florida Medicaid AKL required decidedly less. It required only a "knowing" violation defined as:

> [an act] 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.

Fla. Stat. § 409.920(1)(d) (emphasis added). Recognizing this contradiction, the Florida legislature enacted legislation redefining "knowing" as:

> [an] act done voluntarily and intentionally and not because of mistake or accident. "Knowingly" also includes the word "willfully" or "willful" which, as used in this section, means that an act was committed voluntarily and purposely, with the specific intent to do something the law forbids; that is with bad purpose either to disobey or disregard the law.

The Staff Analysis and Economic Impact Statement accompanying this recent Florida legislation specifically referred to the Circuit and Districts' courts decisions holding that the Federal AKL preempted the Florida Medicaid AKL in part because of the contradictory *mens rea* requirements. See S. 2004-1064, at 10-

11 (2004). By redefining the term "knowingly" to match the Federal AKL *mens rea* requirement, the Florida legislative expressly affirmed the Circuit and District Courts' preemption determination as to the *mens rea* requirement.

. HHS-OIG's Statements Regarding Preemption Do Not Relate to the Type of Implied Conflict Preemption Presented Here.

Appellant points to statements by HHS-OIG made in preamble discussions to its regulatory safe harbors to support its contention that preemption is not warranted. See App. Br. at 19. The HHS-OIG statements cited by Appellant merely state the obvious -- "[t]here is no federal preemption provision under the [Federal AKL]." 56 Fed. Reg. 35952, 35957 (July 29, 1991). In other words, the statute does not contain an express preemption provision. There is no indication that HHS-OIG, in making its statement in 1991, had undertaken an implied preemption analysis required under the Supreme Court's preemption doctrine and the Supremacy Clause, i.e., a comparative analysis of state and federal provisions resulting in a determination that no significant conflicts existed between any particular state law and the Federal AKL. Even assuming arguendo that the HHS-OIG statement represented the agency's legal judgment on the constitutional preemption doctrine, such interpretation is not binding on this Court, nor is it entitled to deference because preemption analysis is not within the specialized knowledge or expertise of HHS-OIG. See, generally, Muratore v. United States OPM, 222 F.3d 918, 921-23 (11th Cir. 2000) (suggesting that de novo review may

be appropriate where an agency interpretation is a pure questions of law not within its specialized knowledge).

. The Presumption Against Preemption Does Not Apply to the Florida Medicaid AKL.

Appellant's argument that the Florida Medicaid AKL is entitled to a presumption against preemption also is misplaced. See App. Br. at 9 and 19. As set forth above, Medicaid is a federal health care program, the regulation of which falls within the purview of the federal government. Once a state elects to participate in the Medicaid program, "its Medicaid assistance plan must comply with the federal Medicaid statutes and regulations." See The Public Health Trust of Dade Co. v. Jackson Memorial Hospital, 693 50 2d 562, 564 (Fla. 3rd DCA 1996), citing Harris v. McRae, 448 U.S. 297, 301 (1980). Because the Florida Medicaid AKL regulates the Medicaid program in a manner contradictory to the established purpose of the Federal AKL, it must be preempted.[8]

CONCLUSION

Amicus respectfully requests that this Court affirm the decision below.

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[8] Preemption of the Florida Medicaid AKL does not impact the state's ability to exercise its historic police powers to regulate the delivery of health care in the State of Florida. In that regard, the state has available to it either Fla. Stat. § 456.054, regulating health professions and occupations, or Fla. Stat. § 817.505, prohibiting patient brokering, both of which prohibit kickbacks.

Respectfully Submitted,

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I HEREBY CERTIFY that a true and correct copy of the foregoing Amicus Brief was mailed via First Class Mail this 9th day of December 2004 to:

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