IN THE SUPREME COURT OF FLORIDA

STATE OF FLORIDA,

Appellant,

v.

CASE NO. SC04-613
L.T. CASE NO. 3D03-521

GABRIEL HARDEN, et al.,

Appellee.
_____/

BRIEF OF AMICI CURIAE DAVITA INC., FRESENIUS MEDICAL CARE HOLDINGS, INC. AND GAMBRO HEALTHCARE, INC. IN SUPPORT OF APPELLEES

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INTRODUCTION AND INTEREST OF AMICI

DaVita Inc., Fresenius Medical Care Holdings, Inc. d/b/a/ Fresenius Medical Care North America, and Gambro Healthcare, Inc. (hereinafter collectively "Amici") are corporations that provide products and services throughout the United States for individuals with chronic kidney failure, known as end-stage renal disease ("ESRD"). Through corporate subsidiary entities and/or joint ventures, each corporation owns and operates renal dialysis clinics in Florida and other states, and owns and operates laboratory facilities that provide services to their renal dialysis patients in Florida and other states. The majority of Amici's patients are Medicare or Medicaid recipients. Consequently, Amici are subject to the confusion that results whenever conflicts arise between State legislation and federal Medicaid or Medicare provisions. Amici therefore submit this Brief in support of the Third District Court of Appeal's opinion finding that State legislation standing as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal Medicaid and Medicare Acts, through conflict with 42 U.S.C. § 1320a-7b, violates the Supremacy Clause of the United States Constitution.

Amici are presently challenging Florida legislation that conflicts with provisions of the federally funded Medicare and Medicaid programs. Specifically, Amici seek a declaration that Section 456.053(5)(a), Florida Statutes, of the Florida Patient Self-Referral Act, as recently amended, does not prohibit physicians from referring renal dialysis patients to Amici's subsidiary or joint venture clinics in Florida under a plan of care that includes ancillary laboratory testing at Amici's separate subsidiary laboratories. *Fresenius, et al. v. Dept. of Health, et al.*, Case No. 02-CA-2187. In a companion federal case, Amici contend that if Section 456.053(5)(a) prohibits such referrals, it unconstitutionally conflicts with federal self-referral legislation (commonly referred to as "Stark" legislation, codified at 42 U.S.C. §1395nn(a)(1) and § 1396b(s)) and implementing regulations, which specifically permit such referrals and the payment of claims resulting therefrom.

Amici submit that the State legislation at issue in both these cases should not prohibit Florida physicians and other providers from doing what conflicting federal law expressly permits. A contrary conclusion would only serve to render application of the Medicaid and Medicare programs different in each State. That inconsistency will not only make it difficult for multi-state healthcare organizations such as Amici to deliver services from state to state, but more importantly violates the United States Constitution.

SUMMARY OF THE ARGUMENT

Medicaid and Medicare are healthcare programs governed or controlled by federal law. States must therefore comply with the federal requirements and regulations associated with each of these programs. Medicaid, aimed primarily at providing healthcare to the poor, is funded jointly by individual states and the federal government. Although Medicaid is a joint program, states must comply with the federal requirements and regulations associated therewith in order to receive federal funds. Medicare, aimed primarily at providing healthcare to the elderly and disabled, is fully federally funded and administered. Both programs are subject to the federal anti-kickback statute, 42 U.S.C. § 1320a-7b- and § 1396b(s), (generally precluding patient referrals by a physician to an entity with which the referring entity or individual has a financial relationship). State legislation that conflicts with either of these federal statutes is subject to preemption.

In the instant case, the Third District Court of Appeal properly determined that the federal anti-kickback statute preempts Section 409.920(2)(e), Florida Statutes, because this State statute ignores Congressional wisdom and criminalizes conduct that Congress has expressly determined warrants no penalty. Congress' objective in enacting and amending the federal anti-kickback statute was to establish a uniform system providing certainty for providers. Allowing states to criminalize conduct that Congress has expressly deemed permissible would stand as

an "obstacle" to this objective and improperly prevent the payment of acceptable Medicaid claims. In addition, if states had this authority, they could use it to nullify other congressional requirements and federal agency rules enacted to administer the Medicaid program, as well as the Medicare program. In fact, the Florida Legislature, encouraged by a special interest, recently attempted to amend Section 456.053 to prevent the payment of Medicare claims that federal legislation permits. That amendment to Section 456.053 is the subject of pending State and federal suits by Amici.

To prevent Florida's Legislature from invading the province of Congress with Sections 409.920(2)(e), 456.053, or other statutes, this Court should affirm the decision of the Third District Court of Appeal.

ARGUMENT

I. The Medicaid and Medicare programs

There are two primary federally controlled healthcare programs in this country – Medicaid and Medicare. The Medicaid program was succinctly described by the United States Supreme Court in *Wilder v. Virginia Hosp. Assoc.*, 496 U.S. 498, 503 (1990), wherein the Court stated:

> Medicaid is a cooperative federal-state program through which the Federal Government provides financial assistance to the States so that they may furnish medical care to needy individuals. 42 U.S.C. § 1396. Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services (Secretary). To qualify
>
> for federal assistance, a State must submit to the Secretary and have approved a "plan for medical assistance" 42 U.S.C. § 1396a(a), that contains a comprehensive statement describing the nature and scope of the state's Medicaid program.

Accordingly, participation in the Medicaid program is voluntary, but a participating state must comply with federal law in order to receive federal funds. *See Public Health Trust of Dade County v.*

Jackson Mem. Hosp., 693 So. 2d 562, 566 (Fla. 3d DCA 1996)(recognizing that Florida must comply with federal Medicaid statutes and regulations); *Antrican v. Odom*, 290 F.3d 178, 187 (4th Cir. 2002)(recognizing that when North Carolina chose to participate in the Medicaid program they were required to follow federal Medicaid requirements).

Medicare, by the very terms of Title XVIII of the Social Security Act, is an "entitlement" program, not a public welfare program. 42 U.S.C. § 1395c (2004). In *Fischer v. U.S.*, 529 U.S. 667, 680 (2000), the United States Supreme Court described the purposes of the Medicare program as follows:

> Medicare is designed to the end that the Government receives not only reciprocal value from isolated transactions but also long-term advantages from the existence of a sound and effective health care system for the elderly and disabled. The Government enacted specific statutes and regulations to secure its own interests in promoting the well being and advantage of the health care provider, in addition to the patient who receives care.

Both programs are subject to the terms of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b- and § 1396b(s), which prohibit certain conduct and payment of claims therefore. However, both statutes contain safe harbors and exceptions for conduct that might otherwise be prohibited based on determinations that such conduct will not lead to abuse.

In the instant case, the Third District Court of Appeal concluded that the Florida Legislature, by enacting Section 409.920(2)(e), attempted to remove from a federal safe harbor provision in the federal anti-kickback statute conduct that Congress deemed permissible. The parties in this case have therefore addressed in their briefs the impact of Section 409.920(2)(e) on specific provisions within the federal anti-kickback statute. The Court's decision in this case, however, has the potential to extend beyond this particular State statute and federal provision at issue, and to affect other federal healthcare program provisions, including provisions regulating

the federally funded Medicare program. Accordingly, Amici submit this brief to emphasize the broad and far reaching impact the Court's decision may have on both Medicaid and Medicare and other federal healthcare programs.[1]

II. Florida cannot constitutionally prohibit what federal law expressly permits.

A federal statute will preempt state law where "Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Gade v. Nat'l Solid Wastes Management Association,* 505 U.S. 88, 98 (1992)(citations omitted). In the absence of an explicit preemption clause, there are two types of implied preemption: 1) "field pre-emption, where the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'" or 2) conflict preemption. Conflict preemption arises: a) where it is physically impossible to comply with both state and federal law, or b) where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* Implied preemption occurs where, as here, state legislation conflicts with provisions of federal law that govern federally controlled healthcare programs, in particular the exceptions and safe harbor provisions recognized within those programs.

A. Section 409.920(2)(e), conflicts with and is therefore preempted by provisions of the federal anti-kickback statute.

Creating an obstacle to Medicaid's implementation of its safe harbor provisions, as Section 409.920(2)(e) does in this case, is tantamount to non-

[1] Amici ask that the Court take judicial notice that there are other federal healthcare programs, including programs for veterans, military personnel, federal employees, and retired persons and their families.

compliance with federal law. The State presents essentially two arguments in an effort to establish that Section 409.920(2)(e) does not pose such an obstacle. First, Appellant argues that because both statutes are aimed at curtailing fraud and abuse, a more stringent law in Florida does not require a finding of preemption. Appellant's Brief p. 16. However, in *Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 364-65 (2000)*, the United States Supreme Court held that a state statute penalizing individuals and conduct that Congress explicitly exempted from sanctions was preempted by federal law. The Court expressly stated: "[s]anctions are drawn not only to bar what they prohibit but to allow what they permit…" *Id.* at 366. The Court recognized that the fact that the statutes were aimed at a common end "hardly neutralizes conflicting means." *Id.* at 365. Likewise, the fact that Florida and federal law are both aimed at preventing fraud does not give the State the power to criminalize conduct which federal law explicitly permits. *See Id.* at 366.

The State cites *Commonwealth of Pennsylvania v. Morris*, to support the argument that a more stringent state law is permissible. 575 A.2d 582 (Pa. Super. 1990). Appellant's Brief p. 17. However, *Morris* is clearly distinguishable from the present situation. In *Morris*, the Pennsylvania Supreme Court determined that a state theft statute was not preempted by a penalty provision of the Social Security Act governing the same conduct. However, unlike the present situation, in *Morris*, the Pennsylvania statute merely imposed a more severe penalty for conduct that *Congress likewise determined should be penalized*. In the present situation, the State is attempting to ignore Congressional wisdom and criminalize conduct that

Congress has *expressly determined warrants no penalty*.

The State's second argument in support of Section 409.920(2)(e) is that Congress intended that the states enforce their own fraud laws. However, the applicable legislative history confirms that any authority Congress gave the states does not extend to allow states to prohibit conduct that Congress expressly permits.

Congress first enacted the federal anti-kickback provisions in 1972. *See* Pub. L. 92-603 (Oct. 30, 1972). As first enacted, the provisions were much more narrow than the present form as they prohibited only rebates, bribes, and kickbacks. The anti-kickback legislation was extended to "any remuneration" in 1977. Pub. L. 95-142 (Oct. 25, 1977). In support of their argument, the State cites language from a committee report relating to the 1972 legislation stating that the anti-kickback penalties "would be in addition to and not in lieu of any other *penalty provisions* of state or federal law." *See* Appellant's Brief p.18; HR Rep. 92-231, 5094 (May 26, 1971). While this language suggests states were free at the time to impose *penalties* greater than those imposed by the federal anti-kickback statute, nothing therein suggests that Congress intended to allow states to prohibit *conduct* that Congress expressly determined was permitted.

Further, following the broadening of the prohibition in 1977, Congress recognized that the scope of the federal anti-kickback statute was broad and that it created uncertainty for providers of healthcare goods and services. Therefore, Congress passed Public Law 100-93 requiring The Department of Health and Human Resources ("HHS") to promulgate "safeharbors" for permissible financial relationships. Pub. L. 100-93, § 14 (Aug. 18, 1987). In doing so, the committee report specifically recognized:

> It is the understanding of the Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, in

> consultation with the Attorney General, to promulgate regulations specifying payment practices that *will not be subject to criminal prosecution* under the new section 1128B(b) *and* that *will not provide a basis for exclusion from participation in Medicare or the State health care programs* under the new section 1128(b)(7). (emphasis added).

S. Rpt. No. 100-109, 707-708 (Section 14)(July 14, 1987). Therefore, contrary to the State's assertion, Congress did not at all intend to allow states to enforce their own fraud laws to eliminate the safe harbors it expressly directed HHS to create or to provide a basis for exclusion to participate in Medicare or State health programs. Instead, Congress' objective was a uniform system that provided certainty to providers. Allowing states to penalize conduct that Congress has expressly deemed permissible would certainly stand as an "obstacle" to this objective.[2] *See Crosby*, 530 U.S. at 366.

New York State Dept. of Social Servs. v. Dublino, 413 U.S. 405, 421 (1973) and *Pharmaceutical Research & Mfrs. of America v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001), also cited by the State to support its position, are simply inapposite. In *Concannon*, the First Circuit determined that a Maine prescription drug program was not preempted by Medicaid. 249 F.3d at 77. Specifically, the prior authorization review requirement of the drug program was challenged under the Supremacy Clause as conflicting with the purposes of the Medicaid program. *Id.* at 74. However, unlike the present situation, the Maine Act was not contrary to any federal law. *Id.* at 75 (recognizing that federal Medicaid legislation explicitly

[2] The State also cites commentary from HHS in response to comments received to additional safe harbors passed in 1991. Appellant's Brief p. 19. However, there is no indication that HHS undertook any sort of preemption analysis when drafting this response. Additionally, the provisions of the federal anti-kickback statute at issue here, 42 U.S.C. § 1320a-7b, were not promulgated by HHS as rules, but instead are direct statutory authority. Thus, the Senate Committee Report regarding these provisions, quoted above, which indicates that Congress' objective in requiring safeharbors was to provide certainty to providers, would take precedence over any conflicting interpretation of Congressional intent regarding preemption offered by HHS.

permits prior authorization requirements). In fact, the court recognized that the Maine program *complied* with the requirements of federal law. *Id.* (finding the Maine Act incorporated the only limitations placed on prior authorization by federal Medicaid legislation).

Dublino is likewise distinguishable. 413 U.S. at 405. In *Dublino*, the United States Supreme Court determined that "Work Rules" enacted by the state of New York relating to the New York Welfare Program were not preempted by the Social Security Act. However, as in *Concannon*, there was no federal statute at issue with which a conflict was claimed. Instead, the plaintiffs were attempting to argue that the "comprehensive scheme" of the Social Security Act preempted the New York law. *See Id.* at 414. In rejecting this argument, the Court recognized that preemption could occur if a particular provision of the Work Rules contravened specific provisions of the Social Security Act. *Id.* at 700.

This case presents just such a situation. In particular, it involves a provision of State law that is directly contrary to and irreconcilable with provisions of a federal law. As such, the State law must be preempted. *See Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000)(recognizing that a state law is preempted by federal law when it is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress—whether that ?obstacle' goes by the name of conflicting; contrary to; … repugnance; difference; irreconcilability; inconsistency; violation; curtailment; …interference, or the like.").

B. States should not be given the power to nullify provisions of healthcare programs controlled by federal law through the enactment of State

statutes which criminalize conduct or prohibit the payment of claims that the federal government permits.

The State argues that "Congress clearly intended that the states enforce their own laws on fraud." Appellant's Brief p. 9-10. However, if states were free to enforce fraud laws contrary to federal legislation, those laws could be used to criminalize services and void claims for payment under Medicaid and Medicare, including claims that are perfectly legal and valid under federal law.[3]

In fact, it is now being asserted that the 2002 amendment to the Florida Patient Self-Referral Act at Section 456.053, Florida Statutes, invalidates valid Medicare claims despite the fact that both the Florida and Federal Legislatures have recognized that payment of such claims does not encourage or result in abuse of the Medicare program. *See* 60 Fed. Reg. 41914, 41940 (August 14, 1995); *Overview of Kidney Dialysis Studies And Providers of End Stage Renal Disease Care*, Florida House of Representatives, Committee on Health Regulation (October 2001). If Amici's pending challenge to this State legislation fails, the primary result will not be avoidance of abuse, but will be financial benefit to Amici's competitor, who will by default perform and receive Medicare funds for laboratory services previously performed by Amici. It comes as no surprise that Amici's competitor lobbied for the questionable amendment to Section 456.053, which was passed under dubious circumstances.[4] A competitor's special interests do not provide a justifiable basis

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[3] For example, the State could apply Florida's Unfair and Deceptive Trade Practices Act to void Medicare or Medicaid claims that are reimbursable under federal law. Fla. Stat. §§ 501.201-501.203 (2003). *Cf. Congress of California Services v. Catholic Healthcare West*, 87 Cal. App. 4th 491, 510 (Cal. App. 2d 2001)(holding an unfair business practices claim preempted by Medicare).

[4] Senate bill 46-E (subsequently Chapter No. 2002-389), amending Section 456.053, was passed during 2002 Special Session E after almost identical legislation regarding Section 456.053 had failed in the regular session. The law contained

for ignoring federal law.

Section 456.053(5)(a), a part of Florida's Patient Self-Referral Act of 1992, provides that "a health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest." In addition to disciplinary and civil penalty provisions, no claims may be made and any claims paid for services provided in violation of Section 456.053(5)(a) are subject to refund. *See* Fla. Stat. § § 456.053(5)(c), (d), (g) (2003). This provision applies to all referrals by healthcare

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multiple unrelated subjects and was passed without allowing amendments by the House of Representatives. See Complaint filed by Amici in the Circuit Court of the Second Judicial Circuit, *Fresenius, et al. v. Dept. of Health*, Case No. 02-CA-2187.

providers, including referrals for services that are covered and paid for by Medicaid and Medicare.[5]

Florida's Patient Self-Referral Act was modeled after federal self-referral legislation, the federal Ethics in Patient Referral Act ("Stark I"), passed by Congress as part of the Omnibus Budget Reconciliation Act of 1989. *See* Pub. L. 101-239, § 6204 (Dec. 19, 1989). Stark I generally prohibits a physician from referring a Medicare patient for clinical laboratory services to an entity with which the physician has a "financial relationship." 42 U.S.C. § 1395nn(a)(1)(A). In 1993, the prohibition contained in Stark I was extended ("Stark II") to other "designated health services" in addition to clinical laboratory services, and also to include referrals of Medicaid patients. *See* Pub. L. 103-66, §§ 13562, 13624 (Aug. 10, 1993). No claims for payment for clinical laboratory services or other designated health services provided in violation of Stark may be made. *See* 42 U.S.C. § 1395nn(a)(2)(B); 42 U.S.C. § 1396b(s).

The Stark legislation identifies a number of referrals that are expressly permissible and therefore excepted from its prohibition against physician referrals to entities with which the physician has a financial relationship. The Stark legislation also provides for HHS to make additional exceptions "[i]n the case of any other financial relationship which the Secretary determines, and specifies in regulations, *does not pose a risk of program or patient abuse*." 42 U.S.C. § 1395nn(b)(4) (emphasis added). HHS has determined that referrals for ESRD laboratory services that are ancillary to renal dialysis treatment and reimbursed as part of the federal composite rate for most services, do not pose a risk of abuse and thus are not prohibited under federal law.[6] Therefore, under federal law, referrals to an

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[5] The vast majority of Amici's patients qualify for Medicare under the "end stage renal disease program, which is a benefit unique to the Medicare program." *See* 42 U.S.C. § 1395c(3); 42 U.S.C. § 426-1. In fact, approximately 2.4 million beneficiaries of Medicare qualify because they have end-stage renal disease even though they have yet to reach age 65. *See* Centers for Medicare & Medicaid Services, Medicare Beneficiaries: Source of Eligibility & Coverage, 2002 (June 2002), *available at:* http://www.cms.hhs.gov/medicare/ (last visited July 1, 2004).

[6] *See* 42 C.F.R. § 411.351 (defining "designated health services" to specifically exclude "services reimbursed by Medicare as part of a composite rate"); 69 Fed. Reg. 16054, 16111 (Mar. 26, 2004)(recognizing that a separate exemption for ESRD composite rate services, including ESRD laboratory services, is unnecessary because they are excepted under 42 C.F.R. 411.351 as they are reimbursed on a composite rate); *See* 60 Fed. Reg. 41914, 41940 (Aug. 14, 1995)(recognizing that services provided under the ESRD composite rate do not pose a risk of patient or program abuse). The

ESRD facility for services reimbursed under the Medicare composite rate, which includes but is not limited to laboratory services, are not prohibited and claims for payment made by providers of such services are valid and will be paid by the federal government regardless of whether the referring physician has a financial relationship with the entity performing the laboratory services.[7]

In clear contrast to federal law, Florida's Patient Self-Referral Act, Section 456.053, Florida Statutes, as amended in 2002, does not except from its definition of prohibited referrals, referrals for ESRD laboratory services, which the federal Stark legislation and implementing regulations expressly recognize. *See* 42 C.F.R. § 411.351. Thus, Amici's competitors are urging that, under State law, Amici are prohibited from using their own subsidiary labs to perform labwork for dialysis patients covered by Medicare's composite rate, and that Amici instead are required to send their lab work to a separate competitor lab.[8]

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exceptions in 42 C.F.R. §§411.551 and 411.553 are very recent, taking effect July 26, 2004 and June 26, 2004, respectively. Prior to these changes, 42 C.F.R. § 411.553 contained an exemption from the Stark legislation for clinical laboratory services furnished in an ambulatory surgical center ("ASC") or ESRD facility, or by a hospice if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively. *See* 42 C.F.R. § 411.355(d) (effective until June 26, 2004). Upon making changes to the definition of "designated health service" in 42 C.F.R. § 411.351, whereby services reimbursed as part of a composite rate are not "designated health services," HHS recognized that a separate exception for ACS/ESRD/hospice composite rate services was "redundant" and would cause unnecessary "confusion" and therefore deleted the exception. *See* 69 Fed. Reg. 16054, 16111 (Mar. 26, 2004). However, ESRD services are still exempted as they are no longer within the definition of "designated health service."

[7] Medicare pays for ESRD services, including services provided at a ESRD clinic and the labwork for the ESRD patients, at a composite rate, regardless of whether the same entity performs those services. If the entities performing the services are not related, they must agree to divide the amount received from Medicare or Medicaid in accordance with the services each entity provides.

[8] This arrangement would also give Amici's competitor the ability to demand from Amici an unreasonable portion of the composite rate for the lab services the competitor provides.

The State Legislature, however, cannot ignore federal law and pass legislation that serves as an obstacle to Medicare's purpose and an obstacle to the payment of claims for which Medicare expressly provides coverage. Allowing the State Legislature to determine what Medicare claims for services will be paid, will create a different Medicare program in Florida, and service providers, including Amici, will not know whether their claims for services will be rejected or subject them to civil or criminal penalties. Accordingly, Congress could not possibly have intended to allow states to determine the validity of claims paid by the *federal* government. In *Congress of California Seniors v. Catholic Healthcare West*, 87 Cal. App. 4th 491, 493 (Cal. App. 2d 2001), the Court rejected such a system. There, a union claimed that a hospital included improper expenses in its annual report required by Medicare. *Id.* The union sought, among other relief, disgorgement of unlawfully acquired funds under the state's unfair business practices statute. The court determined that Medicare provider cost reporting and reimbursement statutes and regulations preempted state regulation of Medicare reimbursement, therefore preempting a challenge under the unfair business practice statute. *Id.* at 668. In determining that reimbursement decisions should be made under federal law, the court quoted the trial court in stating:

> In order to adjudicate this case, the court would be required to usurp the function of the responsible agencies and decide which of the union-related costs that CHW has claimed and will claim in the future are Medicare…reimbursable and which, if any are not. *Id.* at 668, n. 12.

The court went on to recognize:

> In more prosaic terms, the Medicare statutes, regulations, manuals, and administrative decisions lead ineluctably to the conclusion that federal law so comprehensively occupies the field of Medicare cost reporting and reimbursement that there remains no room for state involvement. *Id.* at 668.

Likewise, Congress and HHS have made determinations in the form of comprehensive statutes and regulations, including exceptions and safe harbor provisions, as to what claims will be paid under the Medicare program. There simply is no room for various states to supplant these determinations through State legislation, and any attempt to do so should be rejected. *Id.; see also Lawrence County v. Lead-Deadwood Sch. Dist. No. 40-1*, 469 U.S. 256, 270 (1985)(holding a state statute placing additional limits on federal funds disbursed by Congress to local governments was preempted).

III. Conclusion

Allowing various state fraud laws to determine the validity of claims filed under the Medicaid or Medicare programs, contrary to express federal provisions controlling the services provided under those programs, would essentially allow states to nullify paramount federal provisions governing federal healthcare programs. Such an intrusion is prohibited by the United States Constitution. The Court should therefore find, in accord with the Third District Court of Appeal, that Florida's anti-kickback provision, Section 409.920(2)(e), is preempted by the federal anti-kickback provision. To hold otherwise would permit states to void federally allowable claims for healthcare services in the name of preventing fraud and abuse, or even for the benefit of a special interest, despite Congressional determinations that no such potential for abuse exists and that payment of claims for healthcare services is

warranted.

Respectfully submitted,

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I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished via First Class U.S. Mail to the following counsel, this ___ day of August, 2004.

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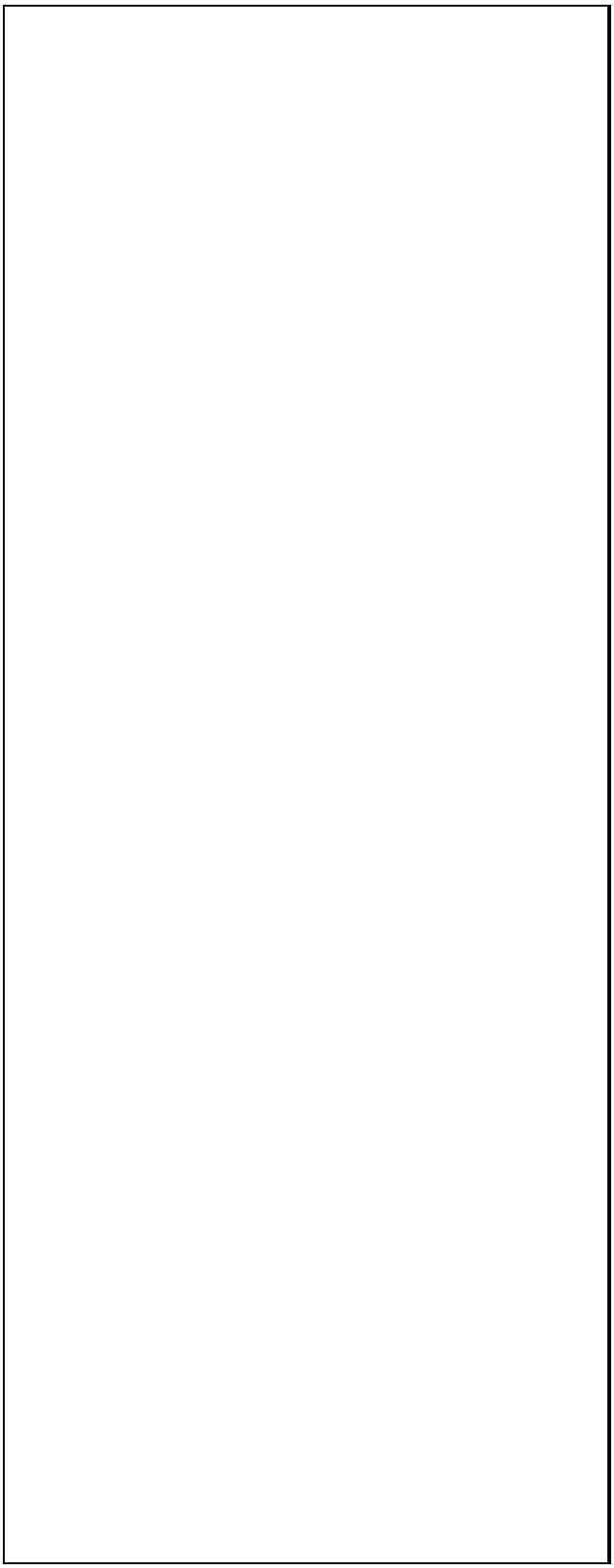

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that this brief complies with the font requirements of Rule 9.210(a)(2) of the Florida Rules of Appellate Procedure.

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Attorney