STATE v. HARDEN

938 So.2d 480 (2006)

STATE OF FLORIDA, Appellant,

v.

GABRIEL HARDEN, et al., Appellees.

No. SC04-613.

Supreme Court of Florida.

May 18, 2006.

Charles J. Crist, Jr., Attorney General, Christopher M. Kise, Solicitor General, Louis F. Hubener, Chief Deputy Solicitor General, Lynn C. Heran, Deputy Solicitor General, and Jason Vail, Assistant Attorney General, Tallahassee, Florida, for Appellant.

G. Richard Strafer, P.A., Miami, Florida, Anthony C. Vitale, P.A., Miami, Florida, Ronald J. Manto of Manto and Kassebaum, LLP, Coconut Grove, Florida, and Charles Wender, Boca Raton, Florida, for Appellees.

M. Stephen Turner, P.A., Kelly A. O'Keefe and Brooke E. Lewis of Broad and Cassel, Tallahassee, Florida, and Gabriel L. Imperato, P.A., of Broad and Cassel, Fort Lauderdale, Florida, on behalf of DaVita, Inc., Fresenius Medical Care Holdings, Inc., and Gambro Healthcare, Inc.; Brit L. Geiger, New York, New York, Gadi Weinreich, and Howard J. Young, Washington, D.C., on behalf of Sonnenschein Nath and Rosenthal, LLP; and Max R. Price and Colleen M. Greene, Miami, Florida, on behalf of Joel M. Berger, D.D.S., As Amici Curiae.

QUINCE, J.

We have on appeal a decision of the Third District Court of Appeal declaring invalid section 409.920(2)(e), Florida Statutes (2000), the "anti-kickback" provision of the Florida Medicaid fraud statute. We have jurisdiction. See art. V, § 3(b)(1), Fla. Const. For the reasons explained below, we conclude that this provision of Florida's Medicaid fraud statute is in conflict with federal law and therefore preempted by it.

FACTS AND PROCEDURAL HISTORY

In December 2000, the Office of the Statewide Prosecutor filed a nine-count information against ten individuals (Gabriel Harden, Edward Polsky, Maria Rodriguez, Bruce Eric Smith, Herbert Lee Goss, Flora Johnson, Elsa Cortorreal, Victor Rivera, Billy Madison, and Von Shella Carter) associated with or "employed by" Dental Express Dentists, Dental Express, Inc., and Express Dental, Inc., three corporate entities providing dental services to children (hereinafter Dental Express). The information charged these individuals with conspiracy, racketeering, and Medicaid fraud under section 409.920(2)(e), Florida Statutes (2000). The State alleged that the defendants engaged in a "pay for patients" scheme in which individuals received "per head" payments in exchange for soliciting and driving Medicaid-eligible children for dental treatment at Dental Express.

The defendants filed motions to dismiss the information, arguing that the payment of wages by a Medicaid provider to its employees for the solicitation and transportation of Medicaid-eligible children to dental facilities for treatment was expressly protected by the federal Medicaid statute and the federal administrative regulation "safe harbor" provisions.[1] Thus, the defendants argued, the State's attempt to prosecute this federally protected activity was unconstitutional under the Supremacy Clause in article VI,

clause 2 of the United States Constitution. Alternatively, the defendants argued that the undefined term "remuneration" in section 409.920(2)(e) was unconstitutionally vague as applied to employer-employee wages. They also argued that the "solicitation" of patients by employees of a legitimate Medicaid provider, when the solicitation involves no intent to defraud, is protected activity under the First Amendment of the United States Constitution and article I, section 9 of the Florida Constitution. In its response, the State conceded that the patients treated by Dental Express were Medicaid-eligible patients. However, the State asserted that the commission-based method of paying the drivers was unlawful under both federal and state law.

After hearing argument from the parties, the circuit court entered an order granting the defendants' motion to dismiss. The circuit court concluded that the State's attempt to prosecute the defendants under the unlawful remuneration provision of section 409.920(2)(e) was preempted by federal law and thus unconstitutional under the Supremacy Clause. The circuit court also held that the mens rea requirement in section 409.920(1)(d) was preempted by federal law and unconstitutional under the Supremacy Clause. Additionally, the circuit court agreed with the defendants' alternative argument that the State's construction of section 409.920(2)(e) as a criminal ban on the solicitation of commercial business would, absent an intent to defraud requirement not contained in the statute, violate the First Amendment and render the statute unconstitutionally vague as applied.

The State appealed the circuit court's ruling to the Third District. The Third District agreed with the circuit court that there is an implied conflict preemption which renders section 409.920(2)(e) unconstitutional. See State v. Harden, 873 So.2d 352 (Fla. 3d DCA 2004). In reaching this conclusion, the Third District noted two significant differences between the federal statute and the Florida statute. First, the federal statute contains "safe harbor" provisions that exclude certain types of payments from being considered "illegal remuneration," including employer-employee payments for the provision of covered items or services such as the transportation of patients for eligible dental services. Based on this distinction, the Third District concluded that Florida's anti-kickback statute criminalizes activity that is protected under the federal statute and "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," thereby resulting in implied conflict preemption. Id. at 355. Second, the federal statute contains a "knowing and willful" mens rea requirement that is not part of the Florida statute. Under federal law, the government must prove that the defendant acted with knowledge that his conduct was unlawful. In contrast, the Florida statute only requires that the defendant act knowingly.[2] The Florida statutory definition of "knowingly" in section 409.920(1)(d) includes mere negligence and consequently criminalizes activity that the federal statute intended to protect. Id. The Third District found these two differences to be dispositive in this case and did not address the other constitutional defects found by the circuit court. Id. at 355 n. 1. Accordingly, the Third District declared the statute unconstitutional.

The State sought review by this Court on the basis of our mandatory jurisdiction to hear appeals of district court decisions declaring a state statute invalid. The Court heard oral argument from the parties and also received several amicus briefs filed in support of the appellees, who were the defendants in the circuit court. The State raises three arguments in its appeal to this Court. The State contends that: neither the federal Medicaid anti-kickback statute nor the federal safe harbor regulations preempts section 409.920(2)(e); the safe harbor regulations do not protect a "per head" payment scheme for the solicitation and referral of eligible Medicaid patients; and section 409.920(2)(e) does not violate the First Amendment and is not constitutionally vague.

LAW AND ANALYSIS

"We review de novo a district court decision declaring a statute unconstitutional." Fla. Dep't of Children & Families v. F.L., 880 So.2d 602, 607 (Fla. 2004). This case involves the confluence of federal and state Medicaid law, specifically those provisions referred to as the "anti-kickback" statutes. Both the federal and state statutes prohibit the payment, offer, solicitation, or receipt of a kickback, bribe, or rebate for referring an individual for services paid for under the Medicaid program or for arranging such services. We are asked to determine whether Florida's statute, which encompasses a wide range of

remunerations within its ambit of prohibited "kickbacks," is preempted by the federal statute and thus unconstitutional under the Supremacy Clause of the United States Constitution. See U.S. Const. art. VI, cl. 2 (stating that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"). In resolving this issue, we begin by reviewing the basic principles of preemption and then we examine the history and language of both the federal and state statutes.

Under the Supremacy Clause, a federal law may expressly or impliedly preempt state law. A state cannot assert jurisdiction where Congress clearly intended to preempt a field of law. See Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981). The United States Supreme Court has recognized three categories of preemption: (1) express preemption where a federal statute contains "explicit pre-emptive language"; (2) implied field preemption, 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"; 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 purposes and objectives of Congress." Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (plurality opinion) (explaining categories of preemption recognized in Supreme Court case law). The federal anti-kickback statute does not contain explicit preemptive language, nor does it contain such a pervasive scheme of federal regulation so as to indicate field preemption. Thus, this case involves the third category of preemption, i.e., implied conflict preemption.

In any preemption case, the court's "ultimate task . . . is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole." Id. (plurality opinion). This involves "looking to the provisions of the whole law, and to its object and policy." Id. (plurality opinion) (quoting Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 51 (1987)). "The nature of the power exerted by Congress, the object sought to be attained, and the character of the obligations imposed by the law, are all important in considering the question of whether supreme federal enactments preclude enforcement of state laws on the same subject." Hines v. Davidowitz, 312 U.S. 52, 70 (1941).

In analyzing a claim of preemption, a reviewing court assumes "that the historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." Pharm. Research & Mfrs. of America v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001) (quoting Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res., 232 F.3d 8, 14-15 (1st Cir. 2000)), aff'd538 U.S. 644 (2003). Federal preemption of a state law is "strong medicine," and is "not casually to be dispensed." Id. (quoting Grant's Dairy, 232 F.3d at 18). This is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism." "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one." Id. (quoting Wash. Dep't of Soc. & Health Servs. v. Bowen, 815 F.2d 549, 557 (9th Cir. 1987)); see also Pharm. Research & Mfrs. of America v. Walsh, 538 U.S. 644, 666 (2003) ("The presumption against federal pre-emption of a state statute designed to foster public health has special force when it appears . . . that the two governments are pursuing common purposes.") (citation omitted).

Federal Anti-Kickback Statute

The current federal anti-kickback statute, entitled "Criminal penalties for acts involving Federal health care programs," prohibits illegal remunerations. 42 U.S.C. §1320a-7b(b) (2000). The statute provides that

> whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) 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 a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care

> program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Id. § 1320a-7b(b)(1). The statute also prohibits anyone from "knowingly and willfully offer[ing] or pay[ing] any remuneration" for the same purposes. Id. § 1320a-7b(b)(2). Thus, in order to convict under the federal anti-kickback statute, the government must prove three elements: the defendant (1) knowingly and willfully (2) solicited or received remuneration (3) in return for, or to induce, referral of program-related business. Paragraph (b)(3) of the federal statute lists eight exceptions to which the prohibitions in paragraphs (1) and (2) do not apply. One exception is any payment practice that is specified in the regulations promulgated by the Secretary of the Department of Health and Human Services (HHS). These are the so-called "safe harbors" which are exempt from the anti-kickback prohibitions.

The federal anti-kickback statute was first enacted as part of the Social Security Amendments of 1972, and was primarily concerned with outlawing health care referrals that were considered unethical or inappropriate. See Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). The original statute made it a misdemeanor for any individual to furnish, solicit, offer, or receive any kickback, bribe, or rebate in connection with any item or service for which payment could be made under the Medicare or Medicaid programs. Id. The penalties for violating the statute were fines of up to $10,000 and imprisonment for up to one year. Id. However, several problems arose as to the interpretation of the statute, including the following: there was no mens rea requirement for a violation of the statute; it was unclear what types of business arrangements were precluded by the statute; and the terms "kickback," "bribe," and "rebate" were not defined in the statute. These uncertainties led to conflicting court interpretations of the statute and the test to be applied in determining whether an anti-kickback violation had occurred. Compare United States v. Porter, 591 F.2d 1048 (5th Cir. 1979) (applying a narrow interpretation of the anti-kickback statute) with United States v. Hancock, 604 F.2d 999 (7th Cir. 1979) (rejecting reasoning in Porter and holding that broad interpretation of statute was appropriate).

Congress amended the statute in 1977 by substituting "any remuneration" for the terms "rebate," "bribe," and "kickback"; by increasing the violation from a misdemeanor to a felony; by increasing the possible fine to $25,000 and the possible length of imprisonment to five years; and by excluding two business practices from the scope of the statute, i.e., the practice of discounts and price reductions and payments made to employees under a bona fide employment relationship. See Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4(b)(1), 91 Stat. 1175, 1180-81 (1977). As explained in the legislative history, the statutory amendments were based on a general agreement "that the existing language of these penalty statutes is unclear and needs clarification." H.R. Rep. No. 95-393(II), at 53 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3055. The Office of the Inspector General (OIG) of HHS has explained that the exceptions for certain business practices were prompted by the concerns of "health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution" because "the statute on its face is so broad." Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3088 (Jan. 23, 1989) (explaining the statutory background for proposed safe harbor regulations).[3] The legislative history also specifically states that "an amount paid `by an employer to an employee for employment in the provision of covered items or services' is exempt" from the definition of a kickback. H.R. Conf. Rep. 95-673 (1977), at 41, reprinted in 1977 U.S.C.C.A.N. 3113, 3115. It is this employee payment exception that is at issue here. See 42 U.S.C. § 1320a-7b(b)(3)(B) (2000).

Congress amended the statute again in 1980 by adding a "knowingly and willfully" mens rea element. See Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980). As explained by the House Budget Committee, this amendment was prompted by a "concern[] that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent." H.R. Rep. 96-1167, at 59 (1980), reprinted in 1980 U.S.C.C.A.N. 5526,

5572. Accordingly, Congress amended the statute "to assure that only persons who knowingly and willfully engage in the proscribed conduct could be subject to criminal sanctions." Id.

The anti-kickback statute was amended again in 1987 to establish more statutory exceptions. See Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, §§ 4, 14, 101 Stat. 680, 688-89, 697-98 (1987). These statutory exceptions were designed to assist health care providers in understanding the legal limits of the anti-kickback statute. The Act also required the Secretary of HHS to issue regulations establishing specific financial arrangements that would not violate the anti-kickback statute, referred to as "safe harbors." The proposed regulations took a number of years to be finalized. These safe harbors, which currently number twenty-two,[4] provide immunity from prosecution for behavior that might have violated the anti-kickback statute. The employee safe harbor provides that a remuneration "does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer." 42 C.F.R. § 1001.952(i) (2005). This provision also states that the term employee has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2), the Internal Revenue Code definition of an employee.[5] The employee safe harbor presumes a reduced potential for program abuse because of the greater degree of control that employers are presumed to exercise over their employees. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,981 (July 29, 1991) ("We are confident that the employer-employee relationship is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them.").

The 1987 amendment also gave the Secretary of HHS authority to exclude a violator from participating in federal health care programs and to direct appropriate state agencies to exclude that person or entity from participation in state health care programs as well. See 42 U.S.C. § 1320a-7a(a) (2000). In addition to the criminal penalties, as of August 5, 1997, a violator may also be subject to a civil penalty of up to $50,000 for each act and to an assessment of damages. Id.

As part of the Health Insurance Portability and Accountability Act, in 1996 Congress charged HHS with issuing advisory opinions in response to requests for guidance as to whether a specific business arrangement violates the anti-kickback law. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000-02 (1996) (codified as 42 U.S.C. § 1320a-7d(b)). These advisory opinions require the requestor to fully identify himself or herself and to involve an actual set of facts or a seriously proposed transaction that will be implemented if the requestor receives a favorable advisory opinion. 42 C.F.R. § 1008.11-.15 (2005). The request may also seek advice on the application of the anti-kickback statute or civil money penalties to a set of facts. Id. § 1008.5(a). Notably, the requestor may not seek an opinion as to whether something is fair market value or whether a person is a bona fide employee. Id. § 1008.5(b); see also 42 U.S.C. § 1320a-7d(b)(3) (2000).

Beginning in 1989, the OIG has issued "Fraud Alerts" to Medicaid providers from time to time.[6] These alerts are intended to inform the health care industry about possibly fraudulent and abusive practices within the industry that constitute statutory violations. See Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372 (Dec. 19, 1994). The fraud alerts also create a stronger case of "intent" if the questionable conduct continues after the alert, encourage whistleblowers to report questionable conduct, and create a cautionary effect on the industry. Patricia Meador, Health Care Fraud and Abuse, 1175 Practicing L. Inst./Corp. 21, 43 (2000).

In response to two requests that OIG "clarify the relationship between the [federal anti-kickback] statute and various State laws," OIG responded that "[i]ssues of state law are completely independent of the federal anti-kickback statute and these regulations." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,957 (July 29, 1991). The OIG also noted that there is no federal preemption provision under the statute, so conduct that is lawful under the federal statute or regulations may still be unlawful under state law, and vice-versa. The State cites this commentary as evidence that there is no federal preemption of the Florida statute at issue in this case. However, we do not read this commentary as entirely foreclosing the question of preemption.

As explained above, the absence of an express preemption provision only means that there is no explicit preemption of the Florida anti-kickback statute. The statute may still be subject to implicit conflict preemption. As the Supreme Court explained in Gade, conflict preemption can result when it is impossible to comply with both the state and federal regulations or where the state law is an obstacle to accomplishing the full purposes and objectives of Congress. 505 U.S. at 98.

Gade involved Illinois statutes governing the licensing requirements for hazardous waste equipment operators and workers. The Supreme Court concluded that these state regulations were impliedly preempted because they were in conflict with the federal Occupational Safety and Health Act (OSHA) regulations. The Supreme Court concluded that the "OSH Act as a whole evidences Congress' intent to avoid subjecting workers and employers to duplicative regulation." 505 U.S. at 100 (plurality opinion). The Supreme Court noted that OSHA permits a state to assume responsibility for occupational safety and health standards, but only if it submits a plan that is approved by the Secretary of Labor. Id. at 99 (plurality opinion). In considering the provisions in this section of OSHA as a whole, the Supreme Court concluded that the "implications of the text of the statute evince a congressional intent to preempt nonapproved state regulations when a federal standard is in effect." Id. at 104 n. 2 (plurality opinion).

Unfortunately, the federal anti-kickback statute is silent on state anti-kickback laws and state regulatory schemes. Instead, we look to the statutory differences between the federal and state laws to determine whether these differences warrant conflict preemption in light of the preemption principles explained above.

Florida Anti-Kickback Statute and Preemption

Section 409.920(2)(e), Florida Statutes (2000), which is included in the statute entitled "Medicaid provider fraud," makes it unlawful 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.

A person who violates this subsection commits a felony of the third degree, which is punishable by imprisonment of up to five years and a fine of $5,000. § 409.920(2), Fla. Stat. (2000) ("A person who violates this subsection commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084."). The statute was created in 1991. See ch. 91-282, § 50, Laws of Fla. The statute provided definitions related to Medicaid provider fraud, established penalties for certain types of fraud, and set the statute of limitations for prosecution under the statute. See Fla. H.R. Comm. on Health Care, CS for CS for SB 1000 (1991) Staff Analysis 21 (May 21, 1991) (on file at Fla. Archives). There were no pertinent substantive changes to the statute until 2004, when the Legislature changed the definition of "knowingly" to require a higher scienter level. See ch. 2004-344, § 8, Laws of Fla. However, that higher scienter is not applicable to the instant case, which was prosecuted under the 2000 statute.

The 2000 Florida anti-kickback statute differs from the federal statute in two important respects. First, the Florida statute has a lower mens rea element which permits an anti-kickback violation based on negligent behavior. The Florida statute defines "knowingly" as "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." § 490.920(1)(d), Fla. Stat. (2000) (emphasis added).[7] In contrast, the federal statute applies only to those acts that are performed "knowingly and willfully," which requires proof that "the defendant acted with an evil-meaning mind, that is to say, that he acted with knowledge that his conduct was unlawful." United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (quoting Bryan v. United States, 524 U.S. 184, 193 (1998), in which a federal firearms trafficking law prohibited anyone from "willfully" violating the statutory provision that forbids dealing in firearms without a federal license).[8]

These mens rea elements, which were added to the federal Medicaid anti-kickback statute in 1980, reflect Congressional concern "that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 96-1167, at 59 (1980), reprinted in 1980 U.S.C.C.A.N. 5526, 5572; see also United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996) (noting that "the literal language of this statute might otherwise encompass some types of innocent conduct").

Second, the Florida anti-kickback statute contains no exceptions or safe harbors. Congress was concerned that the federal anti-kickback statute was so broad that "some relatively innocuous commercial arrangements were technically covered by the statute and therefore were subject to criminal prosecution." Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions & Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,518 (Nov. 19, 1999).

Our research has only revealed one other case which addresses the question of preemption of a state anti-kickback statute.[9] In Massachusetts v. Mylan Labs., 357 F.Supp.2d 314 (D. Mass. 2005), the defendants argued that the anti-kickback provision in Massachusetts law was preempted by federal law. The defendants argued that "the lack of a scienter requirement means that certain behavior legal under the federal statute would be illegal under the Massachusetts statute, leading to inevitable conflict." Id. at 325. The Mylan Laboratories defendants cited the Third District's decision in Harden in support of their preemption argument. However, because the argument was raised late in the briefing and because the court found that "the interpretation of the law [on the scienter requirement] is evolving," it deferred ruling on the preemption issue. Id.; see also Boman v. S.E. Med. Services Group, No. 9501957, 1998 WL 1182063, at *10 (Mass. Super. Ct. Jan. 7, 1998) ("The primary difference between the federal anti-kickback statute and the state provisions is that the Massachusetts statutes do not require the action or practice to be knowing and willful.").

Based on the differences between the federal and state statute at issue here, we conclude that Florida's anti-kickback statute criminalizes conduct that federal law specifically intended to be lawful and shielded from prosecution. See legislative history of federal statute discussed supra pp. 10-12 and differences in Florida statute discussed supra pp. 18-20. There is clear congressional intent to exempt compensation paid by employers to bona fide employees for providing covered items or services from those remunerations that constitute prohibited kickbacks under the federal statute. The heightened mens rea of the federal statute also indicates a clear intent that negligent or inadvertent behavior not subject an individual to prosecution under the federal statute.

Both the heightened mens rea requirement and the safe harbor provisions are key elements in fulfilling the purpose of the federal anti-kickback statute, which is to outlaw health care referrals that are unethical. Accordingly, we agree with the Third District that the Florida anti-kickback statute is preempted because it presents an obstacle to the accomplishments of the purposes of the federal law.

Employee Safe Harbor

The State also argues that the employee safe harbor exception to the federal Medicaid anti-kickback statute does not permit the type of "per head" referral payments made here, even if the payments are made to a bona fide employee. The employee exception provides that the prohibition on illegal remunerations is not applicable to "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." 42 U.S.C. § 1320a-7b(b)(3)(B) (2000). The safe harbor regulation further explains that "the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2)." 42 C.F.R. § 1001.952(i) (2005). In explaining the final rule which implemented the safe harbors, the OIG stated that the employee exception permits "an employer to pay an employee in whatever manner he or she chose for having that employee assist in the solicitation of program business and applied to bona fide employee-employer relationships." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,953 (July 29, 1991); see also Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-kickback Provisions, 54 Fed. Reg. 3088, 3093 (Jan. 23,

1989) ("We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts."). In its provision-by-provision analysis of the safe harbors, the OIG explained that Congress expressly limited the employee exception to bona fide employment relationships, which do not include independent contractors; that the IRS definition of employee which establishes the criteria for a bona fide employment relationship under the safe harbor also includes the IRS's interpretation of 26 U.S.C. § 3121(d)(2) as codified in its regulations and other interpretive sources; that a part-time employee who is paid on a commission-only basis can fall within the scope of the employee provision as long as a bona fide employer-employee relationship exists; and that other types of personal service arrangements, while not covered by the employee provision, may be protected under the personal services and management contracts safe harbor provision. 56 Fed. Reg. at 35,981.

Individuals or entities will be exempt from prosecution under the federal anti-kickback laws if the activities in which they engage satisfy the requirements of the safe harbor provisions. See Lissa Bourjolly & Erin Moak, Health Care Fraud, 41 Am. Crim. L. Rev. 751, 767 (2004). In order to fit within a safe harbor, each element of the particular safe harbor must be met. See David W. Ball, Medicare Fraud and Abuse Anti-Kickback Safe Harbor Regulations, 3 S.C. Law. 34, 35 (1991). However, failure to comply with the applicable safe harbors is not a per se violation of the anti-kickback statute. In the preamble to the 1999 safe harbor regulations, OIG states that an arrangement does not have to comply with a safe harbor in order to be legal under the anti-kickback statute. Medicare and State Health Care Programs: Fraud and Abuse, 64 Fed. Reg. 63,518, 63,521 (Nov. 19, 1999). Moreover, in response to several comments, the OIG emphasized that an arrangement is not necessarily suspect because it does not comply with a safe harbor, although it may be suspect under particular circumstances. However, due to substantial uncertainty in the safe harbors, each transaction is likely to be evaluated on a case-by-case basis to determine whether it constitutes an anti-kickback violation. Bourjolly & Moak, 41 Am. Crim. L. Rev. at 766-67. The burden of proof lies with the entity or individual claiming a safe harbor as a defense. Health Care Programs: Fraud and Abuse, 57 Fed. Reg. 3298, 3353 (Jan. 29, 1992) ("The respondent bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances.").

While there are no HHS advisory opinions that address the exact situation presented in the instant case, the OIG has made a number of enlightening statements in the preambles to the safe harbor regulations. In response to comments requesting that the OIG protect marketing and advertising activities because such activities promote competition or do not violate the statute, the OIG noted that many marketing and advertising activities may involve at least technical violations of the anti-kickback statute. Medicare and State Health Care Programs, 56 Fed. Reg. at 35,974. However, the OIG has also stated that many of these marketing and advertising activities should not be subject to prosecution because they are passive in nature and do not involve direct contact with program beneficiaries, or because the individual or entity involved in these promotions is not involved in the delivery of health care. Id.

There is no case law directly on point with the pay arrangement here. However, there are several cases involving payments for referrals. In one case, a federal district court upheld commission-based payments to physicians who referred Medicaid patients to the hospital that employed the physicians. See United States ex rel. Obert-Hong v. Advocate Health Care, 211 F.Supp.2d 1045 (N.D. Ill. 2002). In another case, a Texas appellate court concluded that a contract between a hospital and a recruiter was not a violation of the federal anti-kickback statute because the recruiter was an employee under the safe harbor provision. See New Boston Gen. Hosp., Inc. v. Texas Workforce Comm'n, 47 S.W.3d 34 (Tx. App. 2001). In contrast, the Eleventh Circuit upheld anti-kickback convictions for per-patient payments made to two employees of the Florida Department of Health and Rehabilitative Services (HRS) for referring patients to a drug treatment program funded by Medicaid. See United States v. Starks, 157 F.3d 833 (11th Cir. 1998). The Eleventh Circuit concluded that the HRS employees did not fit within the employee safe harbor because they were not providing "covered items or services" as required by the statute, but were simply paid for referrals to the program; and they did not receive regular salary checks

from the drug treatment program at their place of employment, but clandestinely received checks with false category codes or cash in parking lots and other locations to avoid detection by their coworkers. Id. at 839. The Seventh Circuit also found an anti-kickback violation for cash payments given to an independent cardiac pacemaker sales representative for each Medicare patient that he referred to a medical facility where he was not an employee. See United States v. Polin, 194 F.3d 863 (7th Cir. 1999). The medical facility defendants argued that they had not violated the statute because the pacemaker sales representative recommended the facility to the patients but only a doctor could actually refer the patients to the facility. The Seventh Circuit did not agree with this argument and characterized the arrangement as a "classic case of an illegal kickback" prohibited by the federal statute. Id. at 867.

We note a glaring distinction between the arrangements upheld in Obert-Hong and New Boston and those deemed prohibited in Starks and Polin. The payments deemed legal involved payments to bona fide employees. See Obert-Hong, 211 F. Supp. 2d at 1050 (explaining that the doctors signed employment contracts requiring them to refer patients to the hospital and that the anti-kickback statute was not designed to regulate hospital-physician employment relationships); New Boston, 47 S.W.3d at 36 (explaining that the Texas Workforce Commission found that the individual in question was an employee and not an independent contractor, based on a continuing relationship, training, and methods of compensation which included fringe benefits). In contrast, the payments found in violation of the federal anti-kickback statute involved payments to nonemployees. See Starks, 157 F.3d at 835-36 (describing payment recipients as community health aides in the employ of Florida HRS who were prohibited from accepting any outside employment that might pose a conflict of interest with their work at HRS and obligated to report any outside employment to HRS); Polin, 194 F.3d at 864 (describing person offered cash payments for referring patients to cardiac pacemaker monitoring service as a pacemaker sales representative).

Based on this limited precedent regarding the applicability of the employee safe harbor to various payment arrangements and the stated intent for this safe harbor, we agree with the circuit court and the Third District that the particular pay arrangement at issue here involves protected employer-employee payments for the provision of covered items or services, which are protected from criminal prosecution under the federal statute.

Constitutional Defects

The circuit court also ruled that the Florida statute violates Dental Express's First Amendment right to solicit patients and provide transportation to those patients and is unconstitutionally vague. State v. Harden, No. F00-38785, at 17-20 (Fla. 11th Cir. Ct. Feb. 5, 2003) (order granting defendants' motion to dismiss). On appeal, the Third District found the preemption issue to be dispositive and did not address these constitutional defects. State v. Harden, 873 So.2d 352, 355 n. 1 (Fla. 3d DCA 2004). Because we conclude that the statute is preempted by the federal law, we do not reach these constitutional issues.

CONCLUSION

For the reasons stated above, we agree with the Third District that section 409.920(2)(e), Florida Statutes (2000), is preempted by federal law and thus unconstitutional under the Supremacy Clause. Accordingly, we affirm the decision of the Third District in Harden.

It is so ordered.

PARIENTE, C.J., and WELLS, ANSTEAD, and BELL, JJ., concur.

LEWIS, J., concurs in result only.

CANTERO, J., recused.

NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION, AND IF FILED, DETERMINED.

Footnotes

1. The federal statute specifies certain activities that do not constitute prohibited "illegal remunerations." See 42 U.S.C. § 1320a-7b(b)(3) (2000). Parallel administrative provisions are contained in 42 C.F.R. § 1001.952 (2005).

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2. Section 409.920(1)(d) was amended by the Florida Legislature in 2004 to conform with the federal law on this point. See ch. 2004-344, § 8, at 2392-93, Laws of Fla. This amendment of the mens rea element was in response to the Third District's decision in Harden. See Fla. S. Comm. on Approp. & Fla. S. Comm. Health, Aging & Long-Term Care, CS for CS for SB 1064 (2004), Staff Analysis 10-11 (March 29, 2004) (on file with comm.). As amended, the statute now provides that the term "knowingly" also includes "willfully."

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3. This background statement was repeated by the OIG when it issued the final rule implementing the "safe harbor" regulations two years later. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,952 (July 29, 1991) (codified at 42 C.F.R. § 1001.952 (2005)).

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4. Some commentators list twenty-three safe harbors. This discrepancy is attributed to differences in how they are divided and not to the substantive content of the regulations. The Code of Federal Regulations divides the safe harbors into twenty-two sections. See 42 C.F.R. §§ 1001.952(a)-(v) (2005); see also Solicitation of New Safe Harbors and Special Fraud Alerts, 70 Fed. Reg. 73,186, 73,187 (Nov. 30, 2005) ("To date, OIG has developed and codified in 42 C.F.R. 1001.952 a total of 22 final safe harbors that describe practices that are sheltered from liability."). HHS is required to develop and publish an annual notice in the Federal Register formally soliciting proposals for modifying the existing safe harbors to the anti-kickback statute and for developing new safe harbors. See 42 U.S.C. § 1320a-7d(a) (2000). Thus, the safe harbors are subject to a continual process of refining and modification.

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5. This provision of the Internal Revenue Code defines an employee as "any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee." 26 U.S.C. § 3121(d)(2) (2000).

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6. To date, the OIG has issued twelve individual Special Fraud Alerts. See Solicitation of New Safe Harbors and Special Fraud Alerts, 70 Fed. Reg. 73,186, 73,187 (Dec. 9, 2005); see also HHS Office of Inspector General, Fraud Alerts, Bulletins, and Other Guidance, http://oig.hhs.gov/fraud/fraudalerts.html (last visited May 1, 2006).

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7. The definition of "knowingly" was amended by the Legislature in 2004 to include the word "willfully." See ch. 2004-344, § 8, at 2392-93, Laws of Fla. As amended, the statute now provides:

> "Knowingly" means that the act was done voluntarily and intentionally and not because of mistake or accident. As used in this section, the term "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 that the law forbids, and that the act was committed with bad purpose, either to disobey or disregard the law.

§ 409.920(1)(d), Fla. Stat. (2005).

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8. Prior to the Supreme Court's decision in Bryan, only the Ninth Circuit Court of Appeals had applied a heightened mens rea standard to the federal anti-kickback statute. See Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (construing "knowingly and willfully" as requiring defendants to know that the statute prohibits offering or paying remuneration to induce referrals and to engage in the prohibited conduct with the specific intent to disobey the law). Other circuits have interpreted "willfully" under a middle mens rea standard, which is consistent with the Supreme Court's subsequent decision in Bryan. See United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998) (approving jury instruction which informed jury that knowingly "means that the act was done voluntarily and intentionally, not because of mistake or accident"); United States v. Jain, 93 F.3d 436, 441 (8th Cir. 1996) (concluding that heightened mens rea standard of Medicare anti-kickback statute only required proof that defendant knew that his conduct was wrongful and not that he knew it violated "a known legal duty"); United States v. Neufeld, 908 F.Supp. 491, 496-97 (S.D. Ohio 1995) (declining to follow the Hanlester interpretation of "willfulness" as requiring knowledge of illegality). Commentators have predicted that the standard announced in Bryan will be followed by federal courts in anti-kickback prosecutions. See Robb De Graw, Note, Defining "Willful" Remuneration: How Bryan v. United States Affects the Scienter Requirement of the Medicare/Medicaid Anti-kickback Statute, 14 J.L. & Health 271 (1999-2000). However, even after the decision in Bryan, the Tenth Circuit still applied the higher mens rea standard to an anti-kickback prosecution. See United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000) (requiring proof of specific intent to violate the law). Thus, there is

still some question as to the scienter requirement for a violation of the federal anti-kickback statute. In no cases, however, have the federal courts applied a negligence or inadvertence standard similar to that in Florida's statute.

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9. This lack of cases might be attributable to the fact that some state anti-kickback statutes were drafted to closely follow the federal statute. See, e.g., People v. Palma, 48 Cal.Rptr.2d 334, 338 (Cal. Ct. App. 1995) (explaining that California legislature "was adopting the federal statutes" when it enacted the state anti-kickback statute; thus court looked to federal law for definition of "employee"); see also Colo. Rev. Stat. Ann. § 26-4-1103(2) (2002) (providing a number of exceptions to anti-kickback statute, including any remunerations permitted pursuant to "any safe harbor regulations of the federal department of health and human services").

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