No. 10-1819

IN THE

United States Court of Appeals for the Fourth Circuit

UNITED STATES EX REL. MICHAEL K. DRAKEFORD, M.D.,

Plaintiff-Appellee,

v.

TUOMEY HEALTHCARE SYSTEM, INC.,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of South Carolina

BRIEF OF AMICUS CURIAE AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF DEFENDANT-APPELLANT

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January 10, 2011

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DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER INTERESTS

Pursuant to FRAP 26.1 and Local Rule 26.1, the American Hospital Association ("AHA"), which is an amicus curiae, makes the following disclosures:

1. Is the AHA a publicly held corporation or other publicly held entity? No.

2. Does the AHA have any parent corporations? No.

3. Is 10% or more of the stock of the AHA owned by a publicly held corporation or other publicly held entity? No.

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))? No.

5. Does this case arise out of a bankruptcy proceeding? No.

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STATEMENT OF INTEREST OF AMICUS CURIAE

The American Hospital Association ("AHA") submits this brief amicus curiae in support of Tuomey Healthcare System, Inc. ("Tuomey").[1] This brief is submitted with the consent of all parties. Founded in 1898, AHA is the national advocacy organization for hospitals in the United States. It represents

[1] Pursuant to Fed. R. App. P. 29(c)(5), the AHA states that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person, other than the AHA and its members or counsel, contributed money that was intended to fund preparing or submitting this brief.

approximately 5,000 hospitals, health care systems, and other health care organizations, as well as 37,000 individual members. AHA's mission is to promote high quality health care and health services through leadership and assistance to hospitals in meeting the health care needs of their communities. AHA educates its members on health care issues and advocates on their behalf in legislative, regulatory, and judicial fora as part of its commitment to improving health care policy and health care delivery for the communities that its members serve.

AHA is particularly interested in this case because it presents two matters of first impression in the federal appellate courts concerning the Ethics in Patient Referrals Act, more commonly known as the Stark Law. The first is whether hospitals are entitled to rely on official commentary published by the Centers for Medicare and Medicaid Services ("CMS") in making decisions about how to structure their operations to be compliant with the Stark Law. The second is what evidentiary showing is required to determine the amount the Government may recover—in equity or otherwise—for hospital services furnished pursuant to "referrals" that purportedly violate the Stark Law.

Compliance with the Stark Law is one of the many obligations of the federal health care programs that AHA's member hospitals take seriously and to which they devote significant resources and effort. The Stark Law imposes some of the

most complicated and confusing prohibitions on hospitals of any of the federal health care laws and can result in the imposition of draconian consequences upon a finding of strict liability for a violation. Generally speaking, if a hospital has a "financial relationship" with a physician, a referral prohibition applies to the physician and a billing prohibition applies to the hospital unless the relationship satisfies an exception. See, e.g., 66 Fed. Reg. 856, 864 (Jan. 4, 2001) (a "financial relationship" is "the factual predicate for triggering" the Stark Law's prohibitions).[2]

The Stark Law is complicated enough on its own but it has also been a moving target of ever evolving statutory and regulatory nuances. Alongside each of the three phases of regulation promulgated thus far, CMS has published extensive official commentary responding to public comments and questions about how the Stark Law applies. See 66 Fed. Reg. 856-965 (Jan. 4, 2001); 69 Fed. Reg. 16,054-146 (Mar. 26, 2004); 72 Fed. Reg. 51,012-99 (Sept. 5, 2007). The end result of the statute and its implementing regulations is that the Stark Law has

[2] The referral prohibition states that, unless one of the dozens of technical statutory and regulatory exceptions applies, "the physician may not make a referral to the [hospital] for the furnishing of designated health services" and the billing prohibition states that "the [hospital] may not present or cause to be presented a [Medicare] claim . . . for designated health services furnished pursuant to a referral prohibited under [the Stark Law],". 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a)-(b). These prohibitions apply to hospitals because the term "designated health services" (or "DHS") includes hospital inpatient and outpatient services. See 42 U.S.C. § 1395nn(h)(6)(K).

become one of the most pervasive regulatory statutes in the delivery of health care. It has altered, and re-altered, nearly every aspect of the relationships between hospitals and physicians—relationships that are essential to the efficient delivery of the full range of medically necessary health care that local communities depend on their hospitals to deliver. And because of the confusing and evolving nature of the Stark Law's prohibitions, hospitals acutely rely on the clarifying statements and explanations that CMS has published with regulations, pouring over the text for clues as to whether and how the Stark Law would apply to particular situations. Based on this commentary, which CMS itself describes as "intended to aid the reader in understanding the regulations," hospitals have modified, adapted, and established business relationships with physicians who provide care at their facilities. 72 Fed. Reg. at 51,013.

In this case, the Department of Justice dismissed the rights of hospitals to rely on the CMS commentary when trying to make business decisions that would be compliant with the Stark Law. The Government's rejection of a hospital's reliance on published agency guidance is improper and of great concern to AHA, hospital management, hospital boards of directors, and hospital counsel across the country. Each of these groups regularly relies on CMS's extensive published guidance when navigating the complexities of the Stark Law. Simply put, everyone studies the official commentary as part of deciphering how to structure

business relationships between hospitals and physicians to avoid violating the Stark Law.

This case is also of great import to AHA because if the decision below stands, it will result in the unfair and unfounded recoupment of money by Government without any demonstration of entitlement. The District Court, with no analysis or discussion, appears to have accepted the Government's unsupported assertion of an entitlement to nearly $45 million that it purportedly paid "by mistake" or that "unjustly enriched" Tuomey. But the Government submitted no evidence that it paid $45 million for hospital care provided pursuant to unlawful "referrals." The consequences of violating the Stark Law's prohibitions are draconian, and it is critical that courts require precise evidence before ordering a hospital to pay back tens of millions of dollars received for providing medically necessary care. Fair enforcement of the Stark Law—which is a particular concern for AHA and its members—depends on courts holding the Government and qui tam relators alike to the proper burden of proof in adjudicating allegations of a Stark Law violation.

In the current era where public and private initiatives demand closer working relationships between hospitals and physicians, the importance of fair, clear, consistent, and predictable implementation and enforcement of the Stark Law takes on even greater importance. See, e.g., Statement of the American Hospital

Association on the Importance of Clinical Integration to the Nation's Hospitals and their Patients, Federal Trade Commission, "Clinical Integration in Health Care: A Check-Up" (May 29, 2008) (discussing how concerns and confusion about enforcement of the Stark Law operates as a real and perceived impediment to hospital and physician arrangements that would improve health care delivery, community access to essential services, and enhanced productivity across providers and settings).[3] As hospitals and physicians look for innovative ways to integrate the health care services that they offer—particularly in underserved communities where recruiting and retaining physicians is a challenge—the Court's resolution of the Stark Law issues in this case takes on added significance. The decision below has the potential to inject even greater uncertainty into the Stark Law's prohibitions by severely penalizing a hospital for relying on CMS's own statements as to how the Stark Law applies and by permitting the Government to avoid having to prove any actual entitlement to recoupment of funds paid to a hospital for providing medically necessary care.

SUMMARY OF ARGUMENT

This case presents two points of first impression and critical importance to hospitals throughout the Fourth Circuit and around the country. First, the District Court denied a hospital the protection of reliance on CMS commentary and

[3] Available at http://www.aha.org/aha/testimony/2008/080529-tes-ftc.pdf.

allowed the Department of Justice to disclaim what CMS has specifically told hospitals they can do without running afoul of the Stark Law. That is unacceptable as a matter of law and policy. In deciding this case, the Court should confirm that hospitals can rely on CMS's guidance when making business and health care policy decisions without worrying that the Department of Justice or a qui tam relator proceeding in the name of the Government will come in after the fact and disavow conduct that CMS has clarified is consistent with the Stark Law.

Second, the court below failed to analyze—in any way—whether and how the Government's evidence supported an "equitable" award of over $44 million. In dealing with the sort of harsh, strict liability regime that the Stark Law imposes, it is particularly important for courts to ensure that any judgments rendered are based on evidence that directly and exactly corresponds to the statutory standard. The statutory standard speaks only to payment for services provided "pursuant to" improper referrals. As a matter of judicial precedent, the District Court's judgment is fundamentally flawed because it would allow tens of millions of dollars of liability to be imposed on community hospitals without making any of the clear, precise, and specific findings of fact necessary to demonstrate that an award of this magnitude is appropriate. Where the Government provides no proof of specific services that were provided and paid for pursuant to referrals that violated the Stark

law, it is not entitled to—and the courts cannot "equitably" allow it to—recoup any money paid to hospitals for providing patient care.

Because the Stark Law is essentially a strict liability regulatory regime, it is essential that courts applying the statute render clear decisions that protect a hospital's right to rely on the official CMS guidance and are based upon an interpretation of the law consistent with, and informed by, the applicable regulations, guidance, and case law. The District Court failed to do so in this case, and its judgment should be reversed.

ARGUMENT

I. Hospitals, Their Board Members And Trustees, Affiliated Physicians, And Outside Counsel Routinely Rely On CMS's Guidance In Drafting Contracts And Reviewing Those Contracts For Compliance With The Stark Law.

The District Court decision is fundamentally flawed because it allowed the Government to disavow CMS guidance issued to aid hospitals and other providers in navigating the intricacies of the Stark Law and to deny hospitals protection for reasonably relying on official CMS's guidance explaining how to avoid violating the statute. The Stark Law's basic prohibitions and policy objectives are relatively easy to summarize; in application, however, every aspect of the Stark Law has proven complicated, confusing, and, at times, a moving target for hospital compliance professionals. See United States ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678, 687 n.8 (W.D. Ky. 2008) (referring to the " 'inordinate

complex[ity]' of the Stark law and regulations" which result "in a 'Homeric odyssey' for attorneys attempting to advise clients on the 'troublesome and elusive goal' of compliance") (citation omitted) (alteration in original).

The Stark Law is part of the Medicare statutory scheme that this Court has recognized is "among the most completely impenetrable texts within human experience." Rehabilitation Ass'n of Va., Inc. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994). As one treatise explains, "[m]any of the elements of the Stark Law's basic prohibitions and exceptions are complex, counterintuitive, and in some cases, have been defined, interpreted, redefined, and reinterpreted on multiple occasions by CMS over the past two decades." Sonnenschein Nath & Rosenthal LLP, The Stark Law: A User's Guide to Achieving Compliance at xiv (2d ed. 2009).

Given its broad prohibitions, the Stark Law has the potential to implicate all sorts of common, every day provider-physician arrangements if it were given a sweeping, overinclusive interpretation. But CMS has explained that it has taken care to avoid doing just that. In adopting regulations and providing official commentary, CMS "interpret[s] the prohibitions narrowly and the exceptions broadly, to the extent consistent with the statutory language and intent" to avoid extending the statute's reach "so broadly as to prohibit potentially beneficial financial arrangements." 66 Fed. Reg. at 860; see also id. ("We have attempted to

read the statute narrowly to avoid adversely impacting potentially beneficial arrangements."). The Department of Justice, in litigating this case, has taken the exact opposite stance from CMS—even though CMS is the agency that has been delegated the authority to "oversee[ ] regulatory implementation of the Stark Law" and to promulgate regulations that "clarify and implement the various provisions of the law." Renal Physicians Ass'n v. U.S. Dep't of Health & Human Servs., 489 F.3d 1267, 1269 (D.C. Cir. 2007).

It is of particular concern to AHA and its members that the Department of Justice, in litigating this case, attempted to "trump" the interpretation of the statute published by the agency charged with its implementation. It did this by effectively denying that the guidance offered by CMS in the official agency commentary had any bearing on whether the Stark Law is violated. The Department of Justice asserted that CMS's guidance was irrelevant because the meaning of the Stark Law statute and regulations are "perfectly clear" and "plain on their face." D.E. 492, Pl.'s Mem. in Opp. to Def.'s Proposed Jury Charges at 1 (Mar. 24, 2010); Trial Tr. 1717; see also D.E. 380, Tr. of Mot. Hrg. at 45 (Sept. 30, 2009) (argument by the Department of Justice that the Stark Law and its regulations regarding compensation arrangements "are not really all that difficult to understand or follow"). The Department of Justice's litigation position and the District Court's acceptance of it denies hospitals the right to rely on official agency guidance in

conducting their affairs and making business and health policy decisions based on that commentary to comply with the Stark Law.

Respectfully, the one thing on which almost every judge, practitioner, and scholar to confront the Stark Law agrees is that there is nothing straightforward about how and when the Stark Law's prohibitions and exceptions apply. It is an extremely confusing and complicated statute. See, e.g., American Health Lawyers Ass'n Public Interest Comm., A Public Policy Discussion: Taking the Measure of the Stark Law at 6 (2009) ("Virtually everyone acknowledges the complexity of the Stark Law.");[4] Steven D. Wales, The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals, 27 Law & Psychol. Rev. 1, 10-11 (2003) ("It may not be easy to determine if a physician's practice conforms to these requirements. It certainly is not intuitive."); id. at 21-22 (describing the Stark Law as "a classic example of a moving target" and noting that "[s]ince its initial passage the Stark Law has been described in the following ways: 'confusing,' 'complicated,' 'over-reaching, too complex, and intrusive;' . . . 'chilling' legitimate business; ambiguous; . . . 'the only thing that's clear is just how unclear the Stark Laws are' because of their 'enormous ambiguity[.]' ") (footnotes omitted); Anne W. Morrison, An Analysis of Anti-Kickback and Self-Referral Law in Modern Health Care, 21 J. Legal Med. 351, 378 (2000)

[4] Available at http://www.healthlawyers.org/Resources/PI/Policy/Documents/Stark%20White%20Paper.pdf.

(explaining that "the ambiguity of the language of the statute was an obstacle to understanding whether a particular arrangement is in violation of the statute").

One of the key disputes in this case is how to interpret the "volume or value" element of an "indirect compensation arrangement." By regulation, an indirect compensation arrangement exists if a physician, among other things, "receives aggregate compensation" from a hospital "that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician." 42 C.F.R. § 411.354(c)(2)(ii). The regulations and the CMS commentary unambiguously state that referrals do not include "any designated health service personally performed or provided by the referring physician." 42 C.F.R. § 411.351; see also, e.g., 66 Fed. Reg. at 864 (final rule included a "[r]evision of the definition of 'referral' to exclude services personally performed by the referring physician"). In its commentary, CMS specifically addressed how personally performed services and corresponding facility fees for hospitals fit into the Stark Law's prohibitions. The agency confirmed that a physician's own services performed at a hospital would not constitute a referral even if the hospital's request for payment of a technical or facility fee would be a referral. See 66 Fed. Reg. at 871; 69 Fed. Reg. at 16,063; see also 69 Fed. Reg. at 16,088-89 (explaining, in response to a scenario in which payment to a physician is "inevitably linked to a facility fee" for a hospital service, that a physician may still

"be paid a productivity bonus" for the physician's personally performed work") (emphasis added).

In deciding this case, the Court should make clear that a hospital is entitled to rely on official agency guidance. A plaintiff—whether the Department of Justice or a qui tam relator—cannot disavow official CMS guidance about how the Stark Law applies. AHA's member hospitals, their boards of directors, and their outside counsel regularly turn to the CMS commentary in trying to parse the nuances of the Stark Law's thorny set of prohibitions and exceptions. The Administrator of CMS recently emphasized that it "will not be acceptable if organizations hear one message from CMS and a different message from other agencies both within and outside HHS" because health care entities "need clarity and predictability about the relevant regulatory regime." CMS, Transcript of Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws Transcript at 9 (2010) (statement of CMS Administrator Dr. Don Berwick).[5] That observation applies with force here.

Clarity and predictability are basic tenets of fundamental fairness and due process for entities trying to comply with federal law. To provide predictability for community hospitals trying to make the financial decisions necessary to

[5] Available at http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopAMSessionTranscript.pdf.

maintaining viability in difficult economic times, hospitals navigating the morass of the Stark Law must be reassured that they can rely on the guidance that CMS offered in promulgating regulations under the statute and in the specific directions about how those regulations apply. That is also the only way to ensure fair enforcement of the Stark Law. In litigating a purported Stark Law violation against a hospital, one arm of the Government—the Department of Justice—cannot reject the positions that another arm of the Government—CMS—has taken in implementing, refining, and explaining the Stark Law to hospitals anxious both to comply with the law and to avoid insolvency.

The District Court's judgment, if not reversed, will leave hospitals throughout the Fourth Circuit and around the country in a state of uncertainty as to whether, when, and how the hospitals, their boards of directors, and their outside counsel can rely on CMS commentary in developing and implementing contractual relationships with community physicians. Such uncertainty is especially problematic because of the chilling effect it is already having on hospital efforts to work with physicians to improve the delivery and coordination of health care for patients.

II. Given The Draconian, Strict-Liability Nature Of The Stark Law, Courts Should Require Carefully Detailed And Reliable Evidence Of The Exact Dollar Value Of Referrals Resulting From Violations Of The Stark Law Before Holding A Hospital Liable For Tens Of Millions Of Dollars.

The District Court entered an unfounded and inequitable judgment because it failed to require the Government to provide any precise or meticulous accounting of the exact amount paid for services resulting from improper referrals. That is a problem in this case and for every hospital or other health care provider caught up in alleged violations of the Stark Law. Moreover, given the new Stark Law self-disclosure protocol,[6] it is also a problem for any health care provider who seeks to inform the Government of any sort of inadvertent or technical violation of the statute. Nowhere in the Stark Law is there a requirement to repay unsubstantiated amounts simply because the Government asserts that the claims had some connection to a particular physician among other physicians involved in the patient's care.

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[6] The Affordable Care Act required HHS to establish a Medicare Self-Referral Disclosure Protocol to enable providers, including hospitals, to self-disclose actual or potential violations of the Stark Law and make that protocol available on CMS's website. Pub. L. No. 111-148, 124 Stat. 119, § 6409 (2010). On September 23, 2010, CMS released its Self-Referral Disclosure Protocol. See CMS Voluntary Self-Referral Disclosure Protocol, OMB Control Number: 0938-1106 (Sept. 23, 2010), available at https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf. One required element of a self-disclosure is a financial analysis that sets forth "the total amount" that should be returned to the Government for non-compliance with the Stark Law. Id. at 4.

The Government presented the jury in this case with evidence about the total dollar value of claims identifying as an "attending" or "operating" physician those physicians that the Government asserted had potentially made improper referrals to the hospital under the Stark Law. Because the jury's verdict in favor of Tuomey also included an interrogatory finding that Tuomey had violated the Stark Law, the Government then requested judgment on its equitable claims in the amount of $44,888,651, plus pre- and post-judgment interest. See, e.g., D.E. 511, U.S. Mot. for Judgment on its Common Law Claims at 1 (Apr. 15, 2010); D.E. 511-1, U.S. Mem. in Supp. at 1, 6 (Apr. 15, 2010).[7] Without addressing or analyzing the evidence and without making any findings as to why the judgment was being entered in that amount, the District Court entered partial judgment for the amount the Government requested. D.E. 543, Order (July 13, 2010); D.E. 544, Judgment (July 13, 2010).

That was error and should be reversed. The Government took a shortcut in its proof that should have precluded entry of the $44-million-plus judgment. There was no evidence before the District Court demonstrating that the judgment amount

[7] Notably, in being asked to answer that interrogatory, the jury was left in the dark as to CMS's commentary on how the Stark Law and its regulations apply. The Government once again denied hospitals the right to rely on guidance offered by CMS by objecting to the jury being instructed on any legal principles drawn from the CMS commentary. See Trial Tr. 2117-25. As a result, the jury was ill-informed as to key legal principles involved in the Stark Law's prohibitions, and the jury's answer to the interrogatory regarding the Stark Law was meaningless.

was the total of monies paid for hospital services that resulted from referrals prohibited by the Stark Law. Instead, the only evidence that the Government offered was the total dollar amount of claims that listed certain physicians as an "attending" or "operating" physician for some aspect of a patient's hospital admission or treatment. See Tuomey Br. 46; Trial Tr. 1221-27, 1237, 1241, 1251-53. But the Stark Law does not prohibit payments based on who was the "attending" or "operating" physician during any given procedure. Congress could have said that a hospital may not present a claim for payment where the "attending" or "operating" physician has a financial relationship with a hospital. It did not. CMS similarly could have said, when it promulgated regulations and defined statutory terms, that a doctor's "referrals" includes any hospital admissions in which that doctor served as one of the "attending" or "operating" physicians. It did not either. See 42 C.F.R. § 411.351 (defining "[r]eferring physician" as "a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity").

A hospital is prohibited from seeking Medicare payment only "for designated health services furnished pursuant to a referral prohibited [by the Stark Law]." 42 U.S.C. § 1395nn(a)(1)(B). The Government was mistaken in asserting that it was entitled to recover Medicare payments simply because it had evidence

that one of the physicians involved in a given patient's care might have made an improper referral under the Stark Law. A physician's mere involvement in a patient's care is not the relevant question.[8] The relevant question is what amount was billed to Medicare for designated health services provided pursuant to a prohibited referral from that physician. Id.

The lack of evidence and lack of analysis in awarding an "equitable" judgment of tens of millions of dollars against a hospital providing medically necessary care is of tremendous concern for hospitals around the country. Cases involving a judicial determination of the dollar amount of a hospital's billing for designated health services resulting from referrals that violated the Stark Law are very few and far between. The District Court's decision could well become seminal guidance and be invoked as precedent—and pressure to settle—anytime a plaintiff alleges a Stark Law violation, whether a qui tam relator proceeding under the False Claims Act or the Government.[9]

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[8] It would not be unusual, for example, for the referring physician for a patient operated on by a general surgeon to be the emergency room physician who admitted the patient; or for the referring physician for a gastroenterology procedure to be a patient's general practitioner. The certainty and clarity that Congress and CMS sought to achieve through promulgation of regulations and guidance can only be achieved through precise identification of which procedures and which corresponding claims and payments the statute prohibited.

[9] Allegations of Stark Law violations have come almost exclusively through relators proceeding under the qui tam provision of the False Claims Act. The possibility of a qui tam suit—and corresponding possibility of recovery of a bounty

Affirming the judgment below would compound two separate errors. First, the District Court effectively magnified the already severe consequences of a Stark Law violation by concluding—apparently implicitly and without analysis or discussion—that equity requires a hospital to repay amounts received for any claim listing a physician who has a financial relationship with a hospital, regardless of whether that physician made a referral for all (or any) of the procedures encompassed within that claim and regardless of whether other physicians are also identified on the same claim form. That is contrary to the language of the Stark Law's billing prohibition, which applies only to "designated health services furnished pursuant to a referral prohibited under [the Stark Law]." 42 U.S.C. § 1395nn(a)(1)(B).[10]

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if successful—provides relators with an incentive to stretch the application of the Stark Law in previously unimagined directions.

[10] Significantly, Medicare operates under a "prospective payment system" in which hospitals seek payment for a fixed rate, often for a bundle of services, not for each individual aspect of the care provided. See University of Chicago Med. Ctr. v. Sebelius, 618 F.3d 739, 742 (7th Cir. 2010) (In 1983, Congress "attempted to limit Medicare costs with the prospective payment system (PPS) whereby the government reimbursed hospitals at a federal rate per given service based on a patient's diagnosis at discharge, regardless of actual cost."). For example, inpatient hospital services are paid at a "diagnosis related group" or "DRG" rate that is based on the patient's diagnosis at discharge. See Medicare & Medicaid Guide Explanations and Annotations (CCH) ¶¶ 4202, 4215 (2010). The DRG rate is an all-inclusive payment for a particular patient's hospital stay and can serve as reimbursement for any number of procedures performed during that patient's stay. Id. Here, the Government made no attempt to establish what portion of any DRG claim was attributable to an improper referral and, as a result, may well have swept

And second, the District Court failed to require the Government to prove its case—and its entitlement to the money it sought—by entering judgment in favor of the Government despite the Government's failure to present evidence addressing actual referrals. While there is a possibility that the operating or attending physician listed on a claim for a particular patient may have made a referral for some portion of the designated health services provided to that patient, the Government failed to demonstrate through reliable evidence that the amount of money the Government sought corresponded to "referrals" that violated the Stark Law. That evidentiary shortcoming should have precluded entry of judgment in the amount the Government sought. The Stark Law's billing prohibition does not sweep within its scope any and every procedure billed to Medicare in which a physician may have been involved, without regard to whether the physician made a referral for the designated health service billed.

The errors that led to the District Court's judgment should be corrected by this Court. The Government failed to present evidence demonstrating that the amount it sought as payment by mistake or unjust enrichment was, in fact, billed to Medicare for designated health services provided pursuant to a prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B). Given that failure, it is the judgment of the District

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in payments for multiple procedures where only one such procedure involved a contracting physician as the "operating" physician.

Court, removing nearly $45 million from a medically underserved community, that is unjust, mistaken, and inequitable.

CONCLUSION

For the forgoing reasons, and those in Tuomey's brief, the Court should reverse the District Court's judgment.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 4,825 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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s/ Jonathan L. Diesenhaus
Jonathan L. Diesenhaus

CERTIFICATE OF SERVICE

I certify that on January 10, 2011 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by serving a true and correct copy at the addresses listed below:

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