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A Stark Contrast to Congressional Intent

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A STARK CONTRAST TO CONGRESSIONAL INTENT

Michael Grimes*

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INTRODUCTION

In 1989, Congress added Section 1877 (the Medicare Stark Law) to the Medicare chapter of the Social Security Act (SSA).¹ As originally enacted, the law prohibited clinical laboratories receiving reimbursement from Medicare from making self-referrals.² Shortly thereafter, in 1993, Congress extended the self-referral prohibition to all physicians receiving reimbursement from Medicare.³ In the same legislation, Congress added section 1903(s) of the SSA (the Medicaid Stark Law), which provided that the federal government would no longer reimburse state Medicaid programs for expenditures made to self-referring physicians.⁴ In 1998, the Centers for Medicare & Medicaid (CMS) issued a proposed rule providing that state Medicaid programs *could* use state funds to reimburse self-referring physicians, even if by doing so, they would lose federal funds.⁵ CMS, however, chose not to finalize this portion of the proposed rule.

The Medicaid Stark laws have generated two related and controversial issues. First, despite CMS's proposed rule saying otherwise, the Department of Justice (DOJ) and individual relators⁶ have attempted to utilize the Medicaid Stark Law to sanction individual Medicaid physicians who make self-referrals. Second, relators have premised Medicaid Stark Law violations as a basis for an action under the False Claims Act (FCA)⁷ even though the Medicaid Stark Law does not include an express private right of action.⁸

These issues raise important policy considerations. First and foremost, they ask whether an administrative agency — CMS — or the courts are more qualified to interpret the Medicaid Stark law. This question must weigh the administrative agency's clarity, uniformity, and expertise against the judiciary's ability to interpret the law. This policy consideration will be interwoven throughout the discussion in this Article and specifically addressed in its recommendations provided in Part IV.

Part I of this Article will introduce the applicable regulatory framework and CMS's proposed rule from 1998. Part II will review the four district court opinions whose holdings directly contravene CMS's proposed rule, and thereafter, discusses the many issues surrounding the FCA jurisprudence. Part III will address the use of the FCA to bring Stark Law violations and how it conflicts with congressional intent. Part IV will discuss how conflicting interpretation of the Stark Law challenges the healthcare industry. Part IV will then make several recommendations about how the healthcare

¹ 42 U.S.C. § 1395nn (2012).

² 42 U.S.C. § 1395nn. *See also* JENNIFER O'SULLIVAN, CONG. RESEARCH SERV., RL32494, MEDICARE: PHYSICIAN SELF-REFERRAL ("STARK I AND II"), 1 (2007) (explaining that a physician "self-refers" when he or she refers a patient to a medical facility in which he or she has a financial interest, defined as ownership, investment, or a compensation arrangement with the entity).

³ *See* 42 U.S.C. § 1395nn (2012).

⁴ *Id.*

⁵ Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1704 (proposed January 9, 1998).

⁶ *See* BLACK'S LAW DICTIONARY 1403 (9th ed. 2009) (defining a relator as "a person who furnishes information on which a civil or criminal case is based; an informer").

⁷ 31 U.S.C. §§ 3729–33.

⁸ *See generally* False Claims Act, 31 U.S.C. §§ 3729–33 (2015).

industry and CMS can resolve these open issues. Finally, Part IV will urge the courts to stay or dismiss any further cases under the primary jurisdiction doctrine.

I. BACKGROUND

A. The Regulatory Framework of the Stark Laws

The Medicare and Medicaid programs differ in both function and design. Although Medicare and Medicaid were both implemented to mitigate the effects of a general lack of affordable health care across the United States,⁹ they serve entirely different purposes¹⁰ and each is afforded their own statutory scheme.¹¹

For example, Medicare is an entirely federal program that provides federal funds to participating health care organizations in exchange for rendering a range of medical services to Americans age 65 and older and to younger people with certain disabilities or health conditions.¹² Medicaid, on the other hand, simply offers an incentive to the States to implement their own health insurance programs for the benefit of underprivileged citizens.¹³ If a state chooses to participate in Medicaid, the state partially funds its program, but receives the rest of its funding from the federal government so long as it complies with certain “conditions of participation.”¹⁴ If the state does not accept federal

⁹ See Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (stating that both programs were created “to provide a hospital insurance program for the aged . . . with a supplementary medical benefits program and an expanded program of medical assistance, to increase benefits . . . [and] to improve the Federal-State public assistance programs”).

¹⁰ *Id.*

¹¹ Medicare was enacted under Subchapter XVIII of Title 42, Chapter 7 of the Social Security Act and codified at 42 U.S.C. § 1395. Medicaid was enacted under subchapter XIX of Title 42, Chapter 7 of the Social Security Act and codified at 42 U.S.C. § 1396.

¹² These payments either come directly from the federal government or come through fiscal intermediaries such as insurance companies. Federal Medicare disbursements occur on a periodic basis, often in advance of a provider rendering services. The funds disbursed are calculated based on information provided to HHS by Medicare providers. See *U.S. ex rel. Schubert v. All Children’s Health Sys.*, No. 8:11-cv-01687-T-27-EAJ, 2013 WL 6054803, at *4 (M.D. Fla., November 15, 2013).

¹³ *Supra* notes 11-12 and accompanying text.

¹⁴ The percentage varies by state. On average, States receive 57% of program expenditures from the federal government. The reimbursement is otherwise known as the Federal Medical Assistance Percentage (FMAP) and is determined annually for each State based on a formula that compares a States’ average per capita income level with the national average income level. See Medicaid: By Topic: Financing & Reimbursement, <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/financing-and-reimbursement.html> (last visited Jan. 3, 2016) (hereinafter Medicaid Financing & Reimbursement). The federal payment to the State is referred to as “federal financial participation” or “FFP”; however, the name reimbursement is somewhat misleading because the stream of revenue is actually a series of quarterly advance payments that are based on the State’s estimate of its anticipated future expenditures. The estimates are periodically adjusted to reflect actual experience. In addition, the Secretary of HHS may disallow reimbursement for “any item or class of items” if she believes that a State’s expenditures do not comply with either the Act or CMS regulations. See *Bowen v. Massachusetts*, 487 U.S. 879, 883-85 (1988).

Medicaid funding, it can establish an entirely state-run health insurance program or none at all.¹⁵

Congress recognized the above-mentioned differences between Medicare and Medicaid programs when it enacted the Stark Laws. For instance, in enacting the Medicare Stark Law, Congress prohibited physicians from making self-referrals and created severe penalties for those who do so.¹⁶ But Congress placed the Medicare Stark Law in the Medicare subchapter, and the Medicaid Stark Law in the Medicaid subchapter, within the United States Code.¹⁷ This separate placement demonstrates that Congress did not mean for the *Medicare* Stark Law to apply to *Medicaid* providers.

Instead, Congress enacted the separate Medicaid Stark Law to regulate state Medicaid programs.¹⁸ In passing that law, Congress was not focused directly on physicians, rather, its sole intent was to prohibit the federal government from making payments to state Medicaid programs that reimburse self-referring physicians.¹⁹

B. CMS's Proposed Rule

CMS agreed that based on its plain language, the Medicaid Stark Law only restricted the federal government's payment to each state, but did not prevent each state from using its own funds to reimburse physicians, even those who engaged in self-referrals.²⁰ In 1998, CMS's predecessor, the Health Care Financing Administration (HCFA), issued a proposed rule to implement the Medicaid Stark Law's federal reimbursement restriction and reporting requirements, which provided:

[W]e do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services. The first part of [the Medicaid Stark Law]... is strictly an FFP provision. It imposes a requirement on the Secretary to review a Medicaid claim, as if it were under Medicare, and deny FFP if a referral would result in the denial of payment under Medicare. [The Medicaid Stark Law] does not, for the most part, make [the Medicare Stark Law] that govern[s]

¹⁵ See Medicaid Financing & Reimbursement, *supra* note 14.

¹⁶ See 42 U.S.C. §1395nn (2012). Violators of the Medicare Stark law may be denied payment for relevant services and have to repay any Medicare funds received in connection with the violation. In addition, the physician may incur civil monetary penalties of up to \$15,000 per claim plus three times the amount of the improper payment for a claim that a person knew or should have known was improper. Moreover, the physician may be excluded from participation in all federal health care programs. See JENNIFER STAMAN, CONG. RESEARCH SERV., RS22743, HEALTH CARE FRAUD AND ABUSE LAWS AFFECTING MEDICARE AND MEDICAID: AN OVERVIEW 6 (2014).

¹⁷ See *supra* note 11 and accompanying text (noting the Medicaid Stark Law's separate placement in the U.S. Code).

¹⁸ Laura Laemmle-Weidenfeld & Amy Kaufman, *The Intersection of the Stark Law and Medicaid Claims: Catching Providers in a Legal Quagmire*, AHLA CONNECTIONS 16, 17 (May 2013).

¹⁹ The Medicaid Stark law is codified in the subchapter titled "Payment to States" of the Social Security Act. See 42 U.S.C. §1396b(s) ("No payment shall be made to a State . . . for expenditures for medical . . . service[s] . . . furnished to an individual on the basis of a referral that would result in the denial of payment for the service under [the Medicare subchapter] if such subchapter provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan.").

²⁰ See Laemmle-Weidenfeld & Kaufman, *supra* note 18.

the actions of Medicare physicians and providers of designated health services apply directly to Medicaid physicians and providers. As such, these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services. A State may pay for these services, but cannot receive FFP for them. However, States are free to establish their own sanctions for situations in which physicians refer to related entities.²¹

In other words, in its proposed rule, CMS's predecessor stated that the Medicare Stark Law was not intended to extend its self-referral prohibition to Medicaid, but rather, to ensure that federal dollars were not being used to fund Medicaid providers who made the same type of self-referrals that are prohibited under Medicare.²²

Additionally, CMS's predecessor clarified that physicians must report their financial relationships to the States, who would then determine whether to take any action.²³ CMS concluded that the requirement was on the States to determine whether a physician has a financial relationship with an entity because it was the States who were at risk of losing FFP.²⁴

In the end, however, CMS failed to finalize the Medicaid Stark Law regulations.²⁵ Instead, CMS issued a three-phase final rule that addressed various provisions of the SSA (including reporting requirements of the Medicare Stark Law). In 2001, CMS issued Phase I of its final rule but stated that it intended to address the Medicaid Stark Law in the following Phase.²⁶ But the 2004 Phase II rule again failed to address that law and reserved the issue for future rulemaking.²⁷ Phase III did not include any discussion regarding the Medicaid Stark Law.²⁸

As a result, the healthcare community (and its legal counsel) did not believe that Medicaid physicians were at risk of losing state Medicaid payments for self-referrals or were required to report financial relationships to state Medicaid programs or to CMS.²⁹

²¹ Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1704 (proposed January 9, 1998).

²² See Scott R. Grubman, *Stark's Self-Referral Prohibitions and Medicaid Claims*, GEORGIA HEALTH LAW DEVELOPMENTS 8, 8-9 (Fall 2014), http://www.gabar.org/committeesprogramssections/sections/healthlaw/upload/Health_Law_Section_Newsletter_Fall_2014.pdf (discussing the law's limited application to Medicaid claims).

²³ 63 Fed. Reg. 1704, 1705.

²⁴ *Id.*

²⁵ Grubman, *supra* note 22 at 9-10.

²⁶ See Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg., 939 (proposed Jan. 4, 2001).

²⁷ See Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) 69 Fed. Reg. 16055 (March 26, 2004).

²⁸ See Laura Laemmle-Weidenfeld, *Courts' Acceptance of FCA/Stark Law Theory in Medicaid Cases Expands Further*, AHLA CONNECTIONS 1, 8 (November 2014).

²⁹ *Id.* at 2; see also Megan Phillips, *Recent Stark Law Developments: Is the Medicaid comfort zone coming to an end?*, HEALTHCARE LAW INSIGHTS (May 30, 2014), <http://www.healthcarelawinsights.com/2014/05/30/recent-stark-law-developments-is-the-medicare-comfort-zone-coming-to-an-end> (last visited Jan. 3, 2016) (discussing recent court decisions suggesting that a Medicaid Stark Law violation may also be a False Claims Act violation).

At the very most, health lawyers believed state Medicaid programs that did not develop their own systems for providers to report potential or admitted self-referrals were at risk of losing federal funding.³⁰ Even that assumption was downplayed, since CMS has never restricted federal funding for a Medicaid provider's violation of Medicaid Stark law.³¹ Over a decade later, however, four district courts ruled otherwise.

II. THE JUDICIARY'S CONTRIBUTION

Prior to discussing the four district court cases, the first Section of Part II will introduce the federal False Claims Act. The second Section of Part II will discuss the four district court cases.

A. Introduction to the federal False Claims Act

The federal False Claims Act (FCA)³² is one of the most important and widely used government anti-fraud tools, inside and outside the healthcare context.³³ The FCA imposes civil liability on a person who knowingly submits, or causes someone else to submit, a false or fraudulent claim to the federal government.³⁴ Under the FCA's *qui tam* provision,³⁵ either the Department of Justice (DOJ) or a relator may bring a civil false claim action against the person responsible for the false claim in federal district court.³⁶ The *qui tam* provision awards a successful relator with a share of the trebled penalties and damages recovered from the defendants, plus costs and reasonable attorney fees.³⁷ The DOJ may, but is not required, to intervene and take over prosecution of the claim.³⁸

Whether the DOJ or a relator brings the action, they must prove: (1) that the defendant submitted or caused a third party to submit a "claim" to the government; (2) that the

³⁰ See Laemmle-Weidenfeld, *supra* note 28 at 11 (noting that although Stark Law reporting requirements have been extended to Medicaid, CMS has failed to issue a rule clarifying what is and what is not eligible for federal funding).

³¹ See Grubman, *supra* note 22 (proclaiming that "CMS has never held that Stark's self-referral prohibition applies to Medicaid").

³² 31 U.S.C. §§ 3729-33.

³³ See STAMAN, CONG. RESEARCH SERV., *supra* note 16 at 8 (explaining that "[t]he FCA is a law of general applicability that is invoked frequently in the health care context"); see also Marc S. Raspanti et al., *Who is Enforcing the Stark Law of the United States?* AHLA CONNECTIONS 26 (September 2012) (stating that the federal government recovers \$15 for every \$1 invested in FCA healthcare investigations and prosecutions and recovered over \$34 billion between 1986 and 2012).

³⁴ 31 U.S.C. § 3729.

³⁵ See BLACK'S LAW DICTIONARY 1251 (7th ed. 1999) (providing that *qui tam* is derived from the Latin phrase "*qui tam pro domino rege quam pro si ipso in hac parte sequitur*," which translates as "who sues on behalf of the king as well as for himself").

³⁶ 31 U.S.C. § 3730.

³⁷ 31 U.S.C. § 3730; see also Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, 76 IND. L.J. 525, 528 (2001) (explaining that "in medical fraud cases, the plaintiff's share of the potential recoveries represents a virtual lottery jackpot since trebled penalties and damages accrue for each allegedly tainted patient bill submitted to the government").

³⁸ Raspanti, *supra* note 33 at 26.

claim was false or fraudulent; and (3) that the defendant knew it was false or fraudulent.³⁹ In regards to the second element, whether the claim was false or fraudulent, courts separate “false” claims into two distinct categories: factually false and legally false.⁴⁰ An example of a factually false claim is where a health provider submits a claim to the federal government for services never actually performed.⁴¹ In contrast, a legally false claim might arise if the provider violates an underlying legal obligation under a statute, regulation, or contractual provision but certifies compliance with that obligation.⁴²

A legally false claim depends on the provider certifying compliance with a legal obligation.⁴³ It is fairly well-established that a provider may be found liable for *expressly* certifying, i.e., on a form or invoice submitted to the government, compliance with a legal obligation that the provider did not actually make.⁴⁴ However, a smaller number of courts also accept the *implied* false certification theory.⁴⁵ Under this theory, the court must infer that a defendant certified his compliance with a law based on the facts and circumstances of the situation.⁴⁶ The federal circuits are split on at least two issues relevant to the false certification theory. First, not all circuits recognize the implied certification theory.⁴⁷ Second, the circuits that recognize the implied certification theory do not agree on the appropriate nexus between the violation and the government’s payment.⁴⁸

³⁹ Lisa Michelle Phelps, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1008 (1998).

⁴⁰ Thomas S. Crane & Brian P. Dunphy, *Will the Supreme Court Weigh in? Implied Certification Theory Under the False Claims Act*, HEALTH CARE ENFORCEMENT DEFENSE ADVISORY (Mintz Levin), October 17, 2011, <https://www.mintz.com/newsletter/2011/Advisories/1428-1011-NAT-HCED/web.htm>.

⁴¹ *Id.*

⁴² *Id.* Implicating the FCA through a violation of a separate regulation, statute, or law is sometimes described as a “tainted claim.” See Matthew, *supra* note 37, at 533 (stating “[u]nder the tainted-claims theory, the plaintiff does not allege the claim for payment itself is false or fraudulent, but rather the falsity or fraud is supplied by the ‘taint’ of an entirely separate, underlying violation” of a separate regulation, statute, or law).

⁴³ Crane & Dunphy, *supra* note 40.

⁴⁴ *Id.* (“[E]xpress certification means that the party submitting the claim . . . affirmatively certified compliance with a law.”).

⁴⁵ *Id.* (“Implied certification means that a party had an ongoing obligation to comply with a law irrespective of whether the party submitting the claim made a direct certification of compliance.”). The implied certification theory grew out of the 1986 amendments to the FCA, which lowered the Act’s scienter requirement from “knowing” to “deliberate ignorance” or “reckless disregard” for the truth. After the amendment, a court could more easily infer an implied duty to comply with all applicable federal laws, regulations, rules, and procedures without direct evidence that the defendant knowingly violated the law. Phelps, *supra* note 39, at 1015.

⁴⁶ Crane & Dunphy, *supra* note 40.

⁴⁷ The Second, Third, Sixth, Ninth, Tenth, Eleventh and the DC Circuit Courts recognize implied certification; the remaining Circuit Courts only recognize the express certification theory. *Id.*

⁴⁸ The standard used in the Second, Third, Sixth, and Tenth Circuit Courts require a claim to violate an express prerequisite to payment in order for the claim to be false under the FCA. See *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (“[I]mplied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.”); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 309 (3d Cir. 2011) (“[P]laintiff must show that compliance with the regulation

All of the circuits, however, recognize the false certification theory within the context of the SSA, especially for violations based on the Anti-Kickback Statute.⁴⁹ On the other hand, the DOJ or relators rarely allege an FCA claim based on the Stark law violations.⁵⁰ In an even more rare scenario, the four district court cases discussed in this next Section were the first cases to discuss the Medicaid Stark law as a basis for an FCA claim.⁵¹

B. The Four District Court Cases

The four district court cases all took place around the same time, and three of them took place in the same circuit. *United States ex rel. Baklid-Kunz v. Halifax Medical Center*⁵² was the first case to address the Medicaid Stark law issues. In *Halifax*, the DOJ and relator alleged that the defendants violated Stark law by engaging in financial

which the defendant allegedly violated was a condition of payment from the Government”); *United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (“[O]nly when compliance is a prerequisite to obtaining payment”); *United States ex rel. Conner v. Salina Reg. Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008) (echoing the “prerequisite to the government’s payment” standard). The DC and Eleventh Circuit Courts do not require the underlying violation of law to be a precondition of payment. *See United States v. Sci. Apps. Int Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) (holding that non-compliance with contract terms may give rise to false or fraudulent claims, even if the contract does not specify that compliance with the contract term is a condition of payment); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005). The Ninth Circuit has not expressly decided the standard to use, but has adopted the implied certification theory. *See Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). The First Circuit requires a claim to misrepresent compliance with a material condition for payment. *See State of New York v. Amgen Inc.*, 652 F.3d 103, 110 (1st Cir. 2011) (holding that claims must represent “compliance with a material precondition of Medicaid payment”).

⁴⁹ Congress, in the Affordable Care Act (ACA) of 2010, codified using the Anti-Kickback Statute as a basis for an FCA claim; *see also infra* note 128 and accompanying text.

⁵⁰ *See Raspanti, supra* note 33 (explaining that “the government has not utilized the FCA extensively to enforce the Stark Law”); Matthew Solomson & Donielle McCutcheon, *Fourth Circuit Vacates and Remands Jury Verdict on Stark Violations in FCA Case*, ORIGINAL SOURCE: FALSE CLAIMS ACT ENFORCEMENT AND LITIGATION, April 5, 2012, <http://fcablog.sidley.com/fourth-circuit-vacates-and-remands-jury-verdict-on-stark-violations-in-fca-case/> (“Stark Law rarely forms the basis of a [FCA] action.”). With the exception of the four district court cases discussed in this article, the cases that discuss Stark violations as a basis for an FCA action focus on the Medicare Stark law violations only. *See, e.g., Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997); *U.S. ex rel. Kosenske v. Carlisle HMS, Inc.*, 554 F.3d 88 (3d Cir. 2009). Implicating the FCA through Stark violations are usually predicated on the theory that “the provider engaged in a prohibited financial relationship with a physician, improperly received referrals from that physician, improperly billed Medicare for such referrals, and improperly received Medicare reimbursement pursuant to those referrals.” *See Laemmle-Weidenfeld & Kaufman, supra* note 18. Despite the courts’ acceptance, the use of the Medicare Stark law as a basis for an FCA claim is not without controversy though. *See Matthew, supra* note 37, at 55 (questioning “whether the FCA generally, and the *qui tam* provision specifically is, in fact, an appropriate enforcement vehicle for violations of the medical antifraud statutes “Even the U.S. Supreme Court has directly contradicted itself on this issue.”).

⁵¹ *U.S. ex rel. Schubert v. All Children’s Health Sys.*, No. 8:11-cv-1687-T-27EAJ, 2013 WL 1651811 (M.D. Fla. 2013); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654 (S.D. Tex. 2013); *U.S. ex rel. Baklid-Kunz v. Halifax Med. Ctr.*, No. 6:09-cv-1002-Orl-31DAB, 2012 WL 921147 (M.D. Fla. 2012); *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253-CIV, 2012 WL 2871264 (S.D. Fla. 2012).

⁵² *Halifax*, 2012 WL 921147 (M.D. Fla. 2012).

relationships with a number of physicians and by submitting false claims to the Florida Medicaid program.⁵³ The court, ruling on the defendants' motion to dismiss, held that the government had sufficiently stated a claim that the defendants, by making self-referrals and then submitting claims to the Florida Medicaid program, had caused the state of Florida to submit false claims to the federal government.⁵⁴

There are two notable aspects about this case. First, the court did not hold that Medicaid Stark law prohibits self-referring Medicaid physicians from submitting claims or receiving funds from Florida Medicaid. Instead, the court held that Medicaid Stark law prohibits the federal government from paying a State for services rendered by self-referring physicians, and by submitting a claim to the Florida Medicaid program, the defendants effectively caused the Florida Medicaid program to submit false claims to the federal government.⁵⁵ In other words, the false claims were the claims made by the State program to the federal government, and the defendants caused those claims to be made.

Second, the court simply concluded that the plaintiff sufficiently alleged that the defendants falsely certified compliance with Medicaid Stark.⁵⁶ The court did not address whether the defendants explicitly or impliedly certified compliance, nor did the court address any other element of an FCA action. The court stated that to survive a motion to dismiss, the plaintiff (in this case the government) only needed to generally allege the elements of the action.⁵⁷ The parties later settled.

A year later in *United States ex rel. Osheroff v. Tenet Healthcare Corporation*,⁵⁸ the U.S. District Court for the Southern District of Florida provided more reasoning before finding that the *qui tam* relator had sufficiently alleged that the defendant falsely certified compliance with Medicaid Stark law. In this case, even though the DOJ declined to intervene, the court found that the *qui tam* relator might be able to prove that Tenet impliedly certified compliance with the Medicaid Stark law by submitting annual cost reports (with no express language contained within) to the Florida Medicaid program.⁵⁹ Although the court pointed to the cost reports, it did not fully explain how Tenet might have certified compliance with the Medicaid Stark law.⁶⁰ The parties subsequently settled.

⁵³ *Id.* at *1.

⁵⁴ *Id.* at *3-4.

⁵⁵ *Id.* at *4.

⁵⁶ *Id.* at *3.

⁵⁷ *Id.* at *6 (stating that Rule 9(b) of the Federal Rules of Civil Procedure, which sets forth special requirements for a plaintiff alleging that the defendant committed fraud, "permits knowledge to be alleged generally").

⁵⁸ 2013 WL 1289260 (S.D. Fla. 2013).

⁵⁹ The court determined that Tenet certified compliance with the Medicaid Stark law through its Medicare Provider Agreement and submission of annual cost reports, and that such representation were "enough to ground a claim under the False Claims Act." The court reasoned that "because . . . cost reports submitted to Medicare can form the basis for liability under the False Claims Act, the court arrives at the same conclusion regarding the cost reports submitted to Medicaid, in light of the fact that Medicaid relies on the representations made in the Medicare cost report." See *Tenet*, 2013 WL 1289260 at *7 *n.4*.

⁶⁰ *Id.*

One year later, in *United States ex rel. Parikh v. Citizens Medical Center*,⁶¹ the U.S. District Court for the Southern District of Texas similarly concluded that the Medicaid Stark law could reasonably support an FCA claim.⁶² There are two interesting aspects about this case. First, the court concluded that the defendant may have certified compliance with Medicaid Stark law by submitting certain *Medicare* forms to the federal government.⁶³ It is possible that the district court decided that it was not necessary to conclude whether the defendant certified with Medicare Stark law or Medicaid Stark law while reviewing a motion to dismiss. Second, the district court was operating under the false certification theory, which its reviewing court, the Fifth Circuit Court of Appeals, later rejected in a different case.⁶⁴ Therefore, it is more likely that future defendants facing similar charges of implied false certification will be able to persuade courts to grant their 12(b)(6) motions to dismiss. Nevertheless, this case also settled.

Finally, in *United States ex rel. Schubert v. All Children's Health System*,⁶⁵ the U.S. District Court for the Middle District of Florida was the first to provide a thorough discussion of CMS's proposed rule. The court reasoned that a "rule proposed, but never finally adopted, has no binding force, especially when it conflicts with the plain language of the statute conferring legislative authority."⁶⁶ The court, instead, concluded that CMS's proposed rule has persuasive value only.⁶⁷

The court was willing to apply some value to a proposed rule. It concluded, however, that the proposed rule suggested that the Medicaid Stark law prohibits CMS from paying FFP to a State. Therefore, if a provider caused the state to submit false claims to the federal government, the provider would also violate the Medicaid Stark Law.⁶⁸ The court concluded that "compliance with the Stark Amendment is undoubtedly a prerequisite to the government's payment," but did not provide any additional reasoning for that conclusion.⁶⁹

The court also summarily dismissed many of the defendant's arguments. Specifically, the defendant argued that the Medicaid claims could not be false because the law and regulations that applied to the defendant's conduct were "exceptionally ambiguous," and FCA cases "cannot be predicated on the alleged violation of any ambiguous law or regulation that has not been subsequently clarified."⁷⁰ The court agreed with this proposition and stated that a "claim cannot be knowingly false if it is based on what

⁶¹ 977 F. Supp. 2d 654, 666 (S.D. Tex. 2013).

⁶² *Id.* at 666.

⁶³ *Id.* at 664 (explaining how Citizens allegedly falsely certified a number of different forms, including CMS provider agreements, Medicare enrollment application Form CMS 855-As). Like many of these cases, the physicians at issue participated in both Medicare and Medicaid.

⁶⁴ *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010).

⁶⁵ 2013 WL 6054803 (M.D. Fla. 2013).

⁶⁶ *Id.* at *6.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at *8.

⁷⁰ *Id.*

a defendant believes to be a reasonable interpretation of an ambiguous statute.”⁷¹ The court, however, rejected that the statute was sufficiently ambiguous to dismiss the relator’s claim.⁷² This case later settled as well.

In summary, the four district courts, although with somewhat different reasoning, all determined that Medicaid Stark law could serve as a basis for an FCA claim. The courts made this determination despite the overall consensus that the Medicaid Stark law does not prohibit physicians from submitting claims or receiving money with the States. Instead, the courts determined that the Medicaid providers caused the State Medicaid program to submit false claims to the government because the government was prohibited from paying the States for self-referrals. There is no telling what the definitive outcomes of these cases would have been if they went to trial; however, it is certain that the fact-finder would have considered the factual allegations of knowledge, falsity, and causation in much more detail. The courts, however, determined that the plaintiffs sufficiently alleged the elements of the FCA claim to survive the defendants’ motions to dismiss. This scenario, however, is precisely why the FCA extensive reach is so troubling, and is the topic of the next Section.

C. Irrational Breadth of Prosecutorial Discretion

The intended reach of the FCA is hotly debated, and even the Supreme Court has had a difficult time expressing its limits.⁷³ Inevitably, the circuits do not agree on the FCA’s boundaries either, especially in regards to whether and to what extent there should be a nexus between the violation of a law and the government’s payment.⁷⁴ Notwithstanding these jurisdictional differences, the “tainted-claims” doctrine is deeply entrenched in the circuits’ FCA jurisprudence.⁷⁵ The “tainted claims” doctrine is a wide net catching many recipients of government funds, which should receive more attention.

The government and relators are increasingly bringing FCA claims based on the implied certification theory and these cases are significantly expanding what constitutes a false statement under the FCA.⁷⁶ For instance, relators have attempted to extend the

⁷¹ *Id.*

⁷² *Id.* at *9 (stating that “[t]here is substantial support for Relator’s allegation that the Stark Amendment applies to Medicaid claims through §1396b(s), and Relator adequately alleges that Defendants knowingly and falsely certified compliance with the Stark Amendment”).

⁷³ See Matthew, *supra* note 37, at 554-55 n. 193 (“It is equally clear that the [FCA] was not designed to reach every kind of fraud practiced on the Government”); *id.* (“Debates at the time suggest that the Act was intended to reach all types of fraud, without qualification . . . the court has consistently refused to accept a rigid, restrictive reading.”).

⁷⁴ See *supra* notes 47-48 and accompanying text (detailing the circuits’ disagreement on these issues).

⁷⁵ Implicating the FCA through a violation of a separate regulation, statute, or law is referred to as a “tainted claim.” See Matthew, *supra* note 37, at 533 (“Under the tainted-claims theory, the plaintiff does not allege the claim for payment itself is false or fraudulent, but rather the falsity or fraud is supplied by the ‘taint’ of an entirely separate, underlying violation” of a separate regulation, statute, or law”).

⁷⁶ Susan C. Levy, Daniel J. Winters, & John R. Richards, *The Implied Certification Theory: When Should The False Claims Act Reach Statements Never Spoken or Communicated, But Only Implied*, 38 PUB. CONT. L.J. 131, 135 (2008).

FCA's jurisprudence to violations of nonbinding guidelines, manuals, and policies.⁷⁷ In addition, some circuits have accepted the more extensive reach of the FCA. For example, some circuits do not require any type of nexus between the violation of a law and the condition of payment for that government program.⁷⁸

There are a number of reasons behind the FCA's expanding reach. First, as noted in the preceding paragraph, the courts do not always act as a barrier to expanded FCA claims.⁷⁹ Second, in the 1980s, Congress lowered the FCA's scienter requirement from "knowing" to "deliberate ignorance" or "reckless disregard" for the truth.⁸⁰ Third, and possibly the most significant, the *qui tam* provision of the FCA provides strong financial incentives for relators and the government to bring broad FCA claims.

Continuing off the last point, Congress created the FCA during the Civil War to combat procurement fraud. From the FCA's inception, it incentivized private citizens with knowledge of a fraud to come forward.⁸¹ These incentives are by no means inconsequential, either. Relators stand to gain as much as thirty percent of the damages imposed on the defendant.⁸² The *qui tam* provision distinguishes the FCA from the SSA's antifraud provisions. The FCA is also significantly different from the Stark Laws, which provide neither a private right of action nor the possibility for a private citizen to be awarded for bringing a claim. The FCA's *qui tam* provision's incentives for private citizens to report suspected fraud makes the FCA one of the most powerful and widely used antifraud provisions within the healthcare industry.⁸³

⁷⁷ *Id.* at 139-40; *but see* *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001)(affirming summary judgment on relator's attempt to bring a false claim based on nonbinding guidelines, manuals, and policies).

⁷⁸ *See, e.g., United States ex rel. Sanders v. East Ala. Healthcare Auth.*, 953 F. Supp. 1404 (M.D. Ala. 1996) (holding that the defendant's alleged violation of state medical licensure requirements—which had no direct relationship with Medicare or Medicaid payments—could serve as a valid basis for a False Claims Act claim by submitting Medicare and Medicaid reimbursement claims); *United States v. Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) (holding that a government contractor could be liable for submitting claims for payment while knowing that it violated contractual provisions that are material to the government's decision to pay, even if the contract does not specify that compliance with the contract term is a condition of payment).

⁷⁹ *See supra* note 47 and accompanying text (listing the circuits that do not require a nexus between the violation and a condition of the government's payment).

⁸⁰ *Phelps, supra* note 39, at 1015.

⁸¹ *Sanders*, 953 F. Supp. at 1411; Timothy Stoltzfus Jost, *Optimizing Qui Tam Litigation and Minimizing Fraud and Abuse: A Comment on Christopher Alexion's Open the Door, Not the Floodgates*, 69 WASH. & LEE L. REV. 419, 421 (2012) (stating that the *qui tam* provision was meant to "encourage a rogue to catch a rogue.") (internal citations omitted).

⁸² *See* Joe Carlson, *Stark Threat on Medicaid*, MODERN HEALTHCARE (Aug. 10, 2013), <https://www.modernhealthcare.com/article/20130810/MAGAZINE/308109971> ("[I]nsiders filing those cases stood to gain as much as 30% of each settlement, giving them a strong incentive to file as broad a lawsuit as possible for violations of the Stark law."); *see also* Matthew, *supra* note 37, at 528 ("stating that [p]rivate plaintiffs are attracted to the FCA to challenge medical fraud because the *qui tam* provision of the FCA rewards private parties who bring an action on behalf of the government with up to a thirty percent share of the damages, penalties, or settlement proceeds recovered from defendants").

⁸³ *See* STAMAN, CONG. RESEARCH SERV., *supra* note 16 at 9 (explaining that the "*qui tam* action has been viewed as a powerful weapon against health care fraud . . . [and the] popularity of *qui tam*

The FCA also provides a financial incentive to the federal government.⁸⁴ The incentive is straightforward; the government can apply its share of the proceeds, either from court judgments or settlements, to future enforcement efforts.⁸⁵ The government has the prosecutorial discretion to bring a Stark Law violation either under the actual Stark Law provision or to “bootstrap” the Stark violation to an FCA claim.⁸⁶ The advantage of bootstrapping a Stark violation into an FCA action is the possibility of receiving financial awards under both provisions, which could bring “astronomical” recoveries for the government.⁸⁷

The FCA’s ever-expanding reach and significant financial incentives for relators and the government makes it a prevalent, yet controversial, tool against healthcare fraud.⁸⁸ The FCA is controversial because, in many cases, it simply does not make sense for physicians to challenge these allegations.⁸⁹ Not only do physicians risk paying penalties

actions brought under the FCA may be attributed partially to the fact that successful whistleblowers can receive . . . monetary proceeds”). In 2013, out of the 846-filed FCA cases, relators filed 752 of them (more than any other year in history). In addition, relators earned more than \$387 million in awards. *See 2013 Year-End False Claims Act Update, Publications*, GIBSON DUNN, (Jan. 8, 2014), <http://www.gibsondunn.com/publications/pages/2013-year-end-false-claims-act-update.aspx>.

⁸⁴ *See* Matthew, *supra* note 37, at 529 (writing that “as long as [private prosecutors] are influenced by their own financial self interest, government prosecutors threaten to do the same. . . . [and] [e]ach enforcement agency reaps financial benefits both to the extent that the agency’s deposits are recognized for its enforcement accomplishments, and because the funds agencies collect through enforcement are ultimately the source of appropriations used to finance future antifraud enforcement.”); *see also* Raspanti, *supra* note 33 at 26 (explaining that “the federal government is recovering \$15 for every \$1 invested in FCA healthcare investigations and prosecutions.”).

⁸⁵ *See* Matthew *supra* note 37, at 528 (stating that “the government prefers to prosecute medical fraud under the FCA because public prosecutors, like private *qui tam* plaintiffs, are rewarded by being able to use their share in the proceeds from antifraud cases in future enforcement efforts.”). In 2013 alone, the government recovered \$3.8 Billion in settlements and judgments under the FCA. *See 2013 Year-End False Claims Act Update, supra* note 83.

⁸⁶ “Bootstrapping” refers to use of the FCA to enforce another statutory violation in an attempt to recover awards under both statutory provision. *See* Scott Withrow, *Supplemental Compliance Guidance Recommend Stark and Kickback Compliance Procedures*, WITHROW, MCQUADE & OLSON, LLP (June 20, 2004), <http://www.wmolaw.com/?p=958> (explaining that the government may use the FCA to increase its chances of recovering damages for the defendant’s violation of another statutory provision); *see also* Stephen G. Sozio, *Health Care Reform Includes Aggressive Fraud Initiative: HHS OIG, DOJ, and Congress Ramp Up Enforcement and Prevention Efforts*, JONES DAY (April 2010), http://www.jonesday.com/health_care_reform_includes/.

⁸⁷ *See* Withrow, *supra* note 86 (writing that “bootstrapping Stark . . . into False Claims Act violations allows *qui tam* relators to enforce Stark . . . and adds monetary penalties of up to \$11,000 per claim on top of already staggering [Stark] fines.”); *see also* Sozio, *supra* note 86 (providing that bootstrapping “can very quickly escalate potential liability into the \$100 million range. . . . [i]n addition, civil [FCA] penalties can involve up to \$50,000 in fines and exclusion from federal program participation . . . [and] [a]dding [Stark] civil penalties of \$5,500 to \$11,000 per occurrence lead to astronomical liability.”).

⁸⁸ Some commentators ask whether the FCA’s expanding reach is a result of logic, congressional intent, public policy, or pure self-interest. *See* Matthew, *supra* note 37, at 540, 556 (asking whether increasingly broad FCA enforcement, with “no substantive legal limit,” is in the public interest).

⁸⁹ *2013 Year-End False Claims Act Update, supra* note 83 (stating that because of the enormous costs associated with litigating and FCA claim “may defendants find that—even when they believe the allegations are completely unfounded—it is too risky to take a case to trial”).

under two provisions, but they also run the risk of being excluded from the Medicare and Medicaid programs.⁹⁰ Thus, physicians will likely settle FCA cases to avoid the harshness of either of these two penalties.

If providers do challenge FCA claims, they may file a motion to dismiss, but are unlikely to hold out until trial.⁹¹ This is especially troublesome because, when reviewing defendants' motions to dismiss, courts accept all factual allegations in the light most favorable to the plaintiffs.⁹² As a result, courts will not fully consider whether the defendant knew it was submitting a false claim; whether that defendant caused the state to seek reimbursement for the false claim; whether the defendant certified compliance with the Medicaid Stark Law; and, depending on the jurisdiction, whether compliance with the Medicaid Stark law was a condition of payment by CMS to the state Medicaid program.⁹³

For example, in all four cases discussed above, the courts found that the defendants may have knowingly caused state Medicaid programs to submit false claims to the federal government. The courts reached these conclusions even though Medicaid providers probably were not aware, nor should they have been aware,⁹⁴ that the Medicaid Stark Law prohibits them from making self-referrals or submitting claims to their states' Medicaid programs.⁹⁵ Most specifically, the court in *Schubert* explicitly chose not to

⁹⁰ See Grubman, *supra* note 22, at 11 (explaining that “[f]ew civil healthcare fraud cases reach litigation”); Laemmle-Weidenfeld & Kaufman, *supra* note 18, at 19 (predicting that weighty legal issues “ultimately will be resolved simply by settlement.”); DAVID E. MATYAS ET AL., LEGAL ISSUES IN HEALTHCARE FRAUD & ABUSE 227 (4th ed. 2012) (explaining that few healthcare organizations will litigate FCA claims “for a variety of reasons including, but not limited to: the actual cost of litigation; the fact that the government can exclude the entity from participation in the Medicare and Medicaid programs pending the court’s determination; and, for publicly traded companies or companies entering into a corporate transaction (e.g., a merger or obtaining third-party financing), the “black cloud” that an FCA case can bring to the organization”).

⁹¹ Matyas et al., *supra* note 90; see also Solomson & McCutcheon, *supra* note 50 (stating that “FCA actions almost never go to trial”); 2013 Year-End False Claims Act Update, *supra* note 83 (stating that because of the enormous costs associated with litigating FCA claims, “many defendants find that—even when they believe the allegations are completely unfounded—it is too risky to take a case to trial”).

⁹² U.S. *ex rel.* Schubert v. All Children’s Health Sys., No. 8:11-cv-1687-T-27EAJ, 2013 WL 6054803 at *6, 9 (M.D. Fla. April 29, 2013) (holding that the “Relator adequately allege[d] that Defendants knowingly and falsely certified compliance with the Stark Amendment, and taking the allegations in the light most favorable to the Relator, dismissal . . . is inappropriate.”); U.S. *ex rel.* Baklid-Kunz v. Halifax Med. Ctr., No. 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, *1 (M.D. Fla. Mar. 29, 2012) (reciting the standard of review for a motion to dismiss); U.S. *ex rel.* Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654, 661 (S.D. Tex 2013) (same).

⁹³ See Laemmle-Weidenfeld & Kaufman, *supra* note 18 (arguing that courts must resolve the issues of knowledge, causation, and conditions of payment before imposing liability, but if the parties settle, these issues become “interesting but academic”).

⁹⁴ See Crane & Dunphy, *supra* note 40, at 1008 (explaining that the requisite scienter for a violation of the FCA is “knowing,” which includes “deliberate ignorance” or “reckless disregard for the truth”; also arguing that a Medicaid provider relying on CMS’s proposed rule cannot possess this level of scienter); see also discussion *infra* Part IV.

⁹⁵ See *supra* Part II.B.

consider whether the defendant's actions were based on a reasonable interpretation of the Medicaid Stark law during the motion to dismiss stage.⁹⁶

Regarding causation, all four district courts concluded that the defendants may have caused state Medicaid programs to submit false claims to the federal government.⁹⁷ As discussed in Part I, each year, the federal government uses a formula that compares the state's average per capita income level with the national average income level to determine how much funding⁹⁸ it will allocate to each state's Medicaid program.⁹⁹ However, courts, taking a liberal view of plaintiffs' allegations at the motion to dismiss stage, have accepted as true that physicians may have caused state Medicaid program to submit false claims to the federal government, without considering that claims made by the states to the federal government are based on the Federal Medical Assistance Percentage, and these claims are not affected by self-referring physicians' claims made to the states.¹⁰⁰

Finally, regarding the FCA's falsity element, the four district courts simply concluded that the defendants could have certified compliance with the Medicaid Stark law.¹⁰¹ This reasoning is flawed because unlike *Medicare* providers, who explicitly certify compliance with a number of statutes and regulations, including the Medicare Stark Law, when submitting cost reports and forms,¹⁰² *Medicaid* providers do not explicitly certify compliance with Medicaid Stark Law.¹⁰³ The courts, however, were not willing to sort the technical differences between the defendants' explicit certifications within the Medicare and Medicaid contexts during a motion to dismiss stage.¹⁰⁴

⁹⁶ See U.S. *ex rel.* Schubert v. All Children's Health Sys., 2013 WL 1651811 at *8-9 (M.D. Fla. April 29, 2013).

⁹⁷ See *supra* Part II.B.

⁹⁸ Otherwise known as Federal Medical Assistance Percentage (FMAP). See *supra* note 14.

⁹⁹ See *supra* note 14.

¹⁰⁰ See *supra* note 14 and accompanying text.

¹⁰¹ U.S. *ex rel.* Baklid-Kunz v. Halifax Med. Ctr. 2012 WL 921147, 1 (M.D. Fla. Mar. 29, 2012) (holding that "falsely certifying compliance with Stark in connection with a claim submitted to a federally funded insurance program is actionable under the FCA"); U.S. *ex rel.* Osheroff v. Tenet Healthcare Corp., 2013 WL 1289260, 1, n.1 (S.D. Fla. March 27, 2013) (finding that alleging that the defendant certified compliance with the Medicaid Stark law by accepting a Medicare Provider Agreement and submitting annual cost reports was "enough to ground a claim under the False Claims Act"); U.S. *ex rel.* Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654, 664 (S.D. Tex 2013) (accepting argument that the defendant expressly certified compliance with the Medicaid Stark law by submitting Medicare forms); U.S. *ex rel.* Schubert v. All Children's Health Sys., 2013 WL 6054803 at *8 (M.D. Fla. November 15, 2013) (proclaiming that "compliance with the Stark Amendment is undoubtedly a prerequisite to the government's payment" for Medicaid providers.).

¹⁰² See, e.g., DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE AND MEDICAID SERVICES, OMB No. 0938-0685, MEDICARE ENROLLMENT APPLICATION: INSTITUTIONAL PROVIDERS, CMS 885A, Section 13.A.3., <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf>.

¹⁰³ See, e.g., *Tenet*, 2013 WL 2871264 at *6 (finding that defendant's certification of compliance through its Medicaid provider agreements was enough to support a FCA action).

¹⁰⁴ All defendants in the district court cases were both Medicare and Medicaid providers. See *Halifax*, 2012 WL at *1; *Tenet*, 2013 WL 1289260, at *1; *Parikh*, 977 F. Supp. 2d at 660; *Schubert*, 2013 WL 6054803 at *1.

This Section highlighted both the dangers and the potency of the FCA. The ever-expanding prosecutorial use by the government and individual relators, the likelihood of settlement to occur prior to fleshing out some of the more fact intense inquiries, and the inconsistent and confusing case law behind the false certification theory are the more apparent problems of the FCA's jurisprudence.

III. A STARK CONTRAST TO CONGRESSIONAL INTENT

All four district courts' holdings were in contrast to congressional intent. First, although the plain language of the statute says otherwise, the district courts used Medicaid Stark law to sanction individual physicians.¹⁰⁵ Second, the courts permitted a violation of the Medicaid Stark law to support a private right of action under the FCA, even though the Medicaid Stark law does not include any such private right of action.¹⁰⁶

A. The Medicaid Stark Law

The Medicare Stark law's plain language does not empower the federal government to take action against individual Medicaid providers.¹⁰⁷ At most, the language is ambiguous and Congress has authorized CMS to interpret the language and achieve uniform regulation and enforcement.¹⁰⁸ However, CMS failed to finalize the proposed rule that would have provided such clarity for Medicaid physicians.¹⁰⁹

Although CMS's proposed rule was never finalized, it is supported by general principles of statutory construction. Courts generally presume that Congress "says in a statute what it means and means in a statute what it says."¹¹⁰ Congress adhered to this cardinal canon of statutory construction when it intentionally passed two different statutes — Medicare Stark and Medicaid Stark — to create two different sets of legal obligations.¹¹¹ Congress'

¹⁰⁵ See *infra* II.A.

¹⁰⁶ See *infra* II.B.

¹⁰⁷ See Carlson, *supra* note 82 (explaining that "[r]ather than denying payments to Medicaid providers who violate the Stark law, the 1993 law directed the CMS to withhold from the state Medicaid program the federal matching portion of any claim that violates Stark.").

¹⁰⁸ See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984) (providing that the "Constitution vests the responsibilities for assessing the wisdom of . . . policy choices and resolving the struggle between competing views of the public interest . . . in the political branches."); see also Frederick Liu, *Chevron as a Doctrine of Hard Cases*, 66 ADMIN. L. REV. 285, 287 n. 3 (2014) (explaining that "Congress is presumed to delegate" agencies the authority to resolve ambiguities in statutory meaning) (internal citation omitted); see also *Delegation and Individual Liberties*, JUSTIA, <http://law.justia.com/constitution/us/article-1/03-delegation-of-legislative-power.html> (explaining that "administration of the law requires exercise of discretion, and that 'in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under road general directives.'").

¹⁰⁹ See *supra* notes 25-27 and accompanying text.

¹¹⁰ YULE KIM, CONG. RESEARCH SERV., R97-589, STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS 4 (2008).

¹¹¹ See Laemmle-Weidenfeld & Kaufman, *supra* note 18 (suggesting that because "Medicaid has its own unique set of coverage requirements, a State can cover and reimburse DHS very differently from the way these services are covered and reimbursed under the Medicare program[, therefore,] CMS concluded that Congress was aware of these differences and that the statutory language was

choice to use different language in each of the two Stark Laws illustrates this intent. Specifically, Congress' choice of language in the Medicare Stark law unambiguously prohibits *physicians* from making self-referrals.¹¹² In contrast, in the Medicaid Stark Law, Congress unambiguously bans *the federal government* from reimbursing the States for self-referrals.¹¹³ By negative implication, Congress did not intend to prohibit Medicaid physicians from making self-referrals like it had in the Medicare Stark law.¹¹⁴

The canon of negative implication is strongest, as is the case here, when the *same* Congress created the two statutory provisions.¹¹⁵ In the present case, the same Congress enacted both the Medicare and Medicaid Stark laws in the Omnibus Budget Reconciliation Act of 1993.¹¹⁶ If Congress meant to create the same prohibition of self-referrals in both statutes, it presumably could have used the same language in both. Instead, Congress decided to extend the *impact* of Medicare Stark law, i.e., prohibiting the federal government from subsidizing self-referring physicians, to Medicaid Stark law.¹¹⁷ There is no indication that Congress meant to mandate the very same prohibition of self-referrals on Medicaid providers than it did for Medicare providers. Congress, instead, left the determination of how to deal with self-referring Medicaid physicians up to the states.¹¹⁸

Actions by later iterations of Congress support this conclusion. In the Affordable Care Act (ACA) of 2010, Congress required CMS to establish a Medicare Self-Referral Disclosure Protocol (SRDP), which enables Medicare providers to self-disclose actual or potential violations of Stark Law.¹¹⁹ In return, the ACA authorizes the Secretary of the Health and Human Services (HHS) to reduce the fines for violations of Stark Law as an incentive to self-report.¹²⁰ On its face, however, the SRDP created by CMS applies only

intended to provide CMS 'some flexibility' in applying the Stark Law's prohibitions in the Medicaid context.'").

¹¹² See 42 U.S.C. § 1395nn (“[T]he physician may not make a referral.”).

¹¹³ See 42 U.S.C. §1396b(s) (“No payment shall be made to a State.”).

¹¹⁴ See *Keene Corp. v. United States*, 508 U.S. 200, 206 (1993) (“Where Congress includes language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion”); see also *Laemmle-Weidenfeld & Kaufman*, *supra* note 18 (“Nothing in the [Stark Medicaid law] permits the state Medicaid agencies to deny payments to the DHS providers on the basis of the providers’ financial relationships with physicians, even if that information were available to the Medicaid agencies. Nor did CMS at any time propose including such prohibitions in their regulations. States would need to enact their own laws to accomplish that.”).

¹¹⁵ See *Lindh v. Murphy*, 521 U.S. 320, 330 (1997) (explaining that if Congress considered the two provisions “simultaneously,” Congress’s action was more likely intentional).

¹¹⁶ See *supra* notes 3-4 and accompanying text.

¹¹⁷ See *Laemmle-Weidenfeld & Kaufman*, *supra* note 18.

¹¹⁸ The title of the Medicaid Stark law, “Payment to States,” also supports this theory. 42 U.S.C. §1396b(s). See also *INS v. National Center for Immigrants’ Rights*, 502 U.S. 183, 189-90 (1991) (stating that the title of a statute “can aid in resolving an ambiguity in the legislation text”).

¹¹⁹ DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE AND MEDICAID SERVICES, OMB No. 0938-1106, CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

¹²⁰ *Id.*

to Medicare providers but not to Medicaid providers.¹²¹ In fact, CMS's guidance "does not even acknowledge the possibility of resolving Medicaid-related claims."¹²² Applying the canon *expressio unius est exclusio alterius*¹²³, Congress' application of this program to Medicare physicians, but not Medicaid physicians, shows that Congress did not intend for CMS to take regulatory action against Medicaid physicians for self-referrals.

B. The FCA and Stark Law

Using the FCA as a vehicle to bring enforcement actions for Stark Law violations is contrary to congressional intent.¹²⁴ First, the courts' acquiescence of the FCA's *qui tam* provision for Stark violations is contrary to the very fabric used to create the Stark Laws.¹²⁵ Stark Law (Medicare or Medicaid) does not contain a private right of action.¹²⁶ Moreover, the Stark Laws' legislative history suggests that an implied private cause of action is contrary to Congress' intent.¹²⁷ The legislative history shows that the Stark laws were meant to strengthen the Government's ability to detect and prosecute fraud, not to empower individual relators.¹²⁸

Second, the ACA amended the Anti-Kickback Statute (AKS) to codify the use of the FCA for AKS violations, which expressly extended the FCA's private right of action to the AKS.¹²⁹ Applying *expressio unius est exclusio alterius*, Congress's decision to create this provision under the AKS and not under the Stark Laws provides strong evidence that Congress did not intend to extend the FCA to Stark Law violations.

¹²¹ See Laemmle-Weidenfeld & Kaufman, *supra* note 18 (writing that "[o]n its face and, as we understand it, also in practice, the SRDP is available only for the resolution of Medicare overpayments resulting from claims resulting from Stark violations").

¹²² *Id.*

¹²³ See BLACK'S LAW DICTIONARY (10th ed. 2014)(explaining that this Latin phrase means that "to express or include one thing implies the exclusion of the other, or of the alternative").

¹²⁴ See Matthew, *supra* note 37, at 573 (stating that the judicial acquiescence of the implication of the FCA through Stark violations resulted in a "in a chaotic departure . . . from Congress's original objectives"); *id.* at 528 (explaining that these cases "extend the scope of the FCA far beyond what Congress intended, and abandon the detailed statutory approach to controlling the medical fraud that Congress designed under the . . . self-referral laws").

¹²⁵ *Id.* at 566 (stating that the plain language of the statutes and supporting congressional documents make it clear Congress intended to set forth an exclusively public administrative enforcement structure for the antifraud laws); *id.* at 568 (stating the application of the tainted-claims theory "belie the wisdom of government oversight where . . . [Stark law] cases are concerned"); *id.* at 572 ("Congress made no mention and did not even acknowledge a place for private-party enforcement of the antifraud statutes."); *id.* at 573 ("[A]t no time has Congress sanctioned private enforcement of these statutes. To the extent that the tainted-claims approach does so, it is contrary to Congress's intent.").

¹²⁶ *West Allis Mem'l Hosp., v. Bowen*, 852 F.2d 251, 255 (7th Cir. 1988) (finding that Congress did not intend to provide a private cause of action); see also Matthew, *supra* note 37 at 528 ("By allowing antifraud enforcement to proceed under the FCA, the tainted-claims approach creates a private cause of action where Congress has not.")

¹²⁷ H.R. REP. NO. 95-393(III) (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3040 (reporting that Congress's intent was to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under Medicare and Medicaid programs") (emphasis added).

¹²⁸ *Id.*

¹²⁹ See 42 U.S.C. § 1320a-7b(g).

In conclusion, the four district court opinions directly contravene congressional intent. Medicaid physicians do not violate the Medicaid Stark law by making self-referrals.¹³⁰ In addition, the Medicaid Stark law is not an appropriate basis for an FCA claim. The following Part will provide various recommendations to Medicaid physicians, courts, and CMS to help align these two lines of thought.

IV. RECOMMENDATIONS

Medicaid providers have little guidance on whether Medicaid Stark law can be used as an enforcement tool against them.¹³¹ CMS's proposed rule, although relied on by the healthcare industry for over a decade, has provided no persuasive value to the four district courts. The four district courts, instead, disregarded CMS's intended, yet never finalized, regulatory framework, and defied congressional intent. Two factors allowed for this result: first, CMS failed to finalize its 1998 rule and second, the courts accepted Medicaid Stark law as a basis for FCA claims. These recommendations intend to address both.

A. Recommendations to CMS

A final rule by CMS would resolve the problems discussed in this Article in two ways. First, Medicaid physicians who comply with CMS's final regulation would *ipso facto* comply with Medicaid Stark law. Consider, for example, CMS's proposal for reporting requirements discussed in Part I. Assuming CMS applies the same reporting requirements as promulgated in its proposed rule, Medicaid physicians would be required to report their financial relationships and self-referrals to the states. As long as Medicaid physicians reported financial relationships and self-referrals to their states, courts could not conceivably find that Medicaid physicians, even those making self-referrals, violated the Medicaid Stark law.

Second, neither the DOJ nor *qui tam* relators would successfully allege FCA violations based on the Medicaid Stark law.¹³² Continuing with the example above, Medicaid physicians would insulate themselves from submitting, or causing states to submit false claims simply by reporting all financial relationships to their states. Medicaid physicians, under the same analysis made in the previous paragraph, would be in full compliance with the Medicaid Stark law. As a result, the DOJ and *qui tam* relators could not allege that Medicaid physicians falsely certified compliance with the Medicaid Stark law.

Unfortunately, CMS has not finalized its proposed reporting requirements or any other information that would clarify the ambiguities in the Medicaid Stark law. These

¹³⁰ Theoretically, Medicaid physicians could violate the statute by failing to supply the required reporting information to the State Medicaid program or to the States. This requirement, however, is a nullity at this point due to CMS's failure to finalize the reporting requirements. *See* discussion *infra* Part IV.

¹³¹ *See* Carlson, *supra* note 82 (explaining that CMS has failed by not issuing guidance about the statute's scope); Matthew, *supra* note 37, at 546 (arguing that "these specialized antifraud laws embody such a significant level of ambiguity . . . [and] the application of the FCA to these laws raises questions of consistent and predictable statutory interpretation.").

¹³² This, again, is assuming that the Medicaid provider complied with all regulatory requirements under CMS's hypothetical final rule and the Medicaid Stark law.

ambiguities allow courts to interpret the law as they deem fit. As discussed in this Article, the problems with FCA jurisprudence, especially at the early motion to dismiss stage, may not produce logical outcomes or the results Congress intended.¹³³ Therefore, this Article recommends that CMS should step up to the plate and finalize its 1998 proposed rule.

B. Recommendations to Medicaid Physicians

There is a strong possibility that CMS will not unilaterally act to finalize its 1998 proposed rule.¹³⁴ Fortunately, the Administrative Procedure Act (APA) provides two ways Medicaid physicians can seek to compel CMS to finalize its rule. First, a Medicaid physician, under section 706(1) of the APA, could ask a court to compel CMS to finalize its 1998 proposed rule.¹³⁵ A court, however, will generally compel agency action only if it is shown that the agency has violated a “clear” or “non-discretionary” duty to act.¹³⁶ In this case, Congress neither provided a timeline nor specifically directed CMS to act. Moreover, courts generally refuse to tell an agency how to allocate its resources among an agency’s competing priorities.¹³⁷ As a practical matter, this choice would likely be costly and unfruitful.

¹³³ As the Medicaid Stark law stands, the true intent of Congress will only be carried out if CMS takes action. If, however, Congress wants to change the law in order to reflect an acquiescence of the FCA’s use and private cause of action for the Medicaid Stark law, then Congress needs to make an amendment to the Medicaid Stark law provisions like it did with the AKS. *See supra* note 129 and accompanying text. In fact, Congress attempted to do exactly this in May 2014. The Medicaid Physician Self-Referral Act was introduced in May 2014, which explicitly prevented State Medicaid programs from making a payment to a Medicaid physician who made self-referrals. *See* Medicaid Physician Self-Referral Act of 2014, H.R. 4676, 113th Cong. (2014). Moreover, the bill codified that a violation of Stark constitutes a false or fraudulent claim that is a sufficient basis for FCA liability as well as a private cause of action. § 2(c). The bill, however, died in the same Congress. *See* www.govtrack.us/congress/bills/113/hr4676.

¹³⁴ It is even possible that CMS is conceding the issue and is in accord with the DOJ’s position. According to one article, “a spokeswoman [for CMS] confirmed . . . in an e-mail to Modern Healthcare that the CMS does consider the Stark law applicable to Medicaid claims, even though it has never published final rules on how it would work.” *See* Carlson, *supra* note 82.

¹³⁵ 5 U.S.C. § 706(1). The APA gives the court the authority to review “agency action.” *See* 5 U.S.C. § 704. Agency action includes not only affirmative action, but also an agency’s “failure to act.” *See* 5 U.S.C. § 551(13). The APA provides at least two limitations on a court’s ability to review agency action. First, a statute may preclude judicial review; and second, agency action may be committed to agency discretion by law. *See* 5 U.S.C. § 701(a)(1)-(2). Section 706 of the APA lays out the standard of review, and provides that “a reviewing court [can] compel agency action unlawfully withheld or unreasonably delayed.” *See* 5 U.S.C. § 706(1). n.

¹³⁶ Eric Biber, *Two Sides of the Same Coin: Judicial Review of Administrative Agency Action and Inaction*, 26 VA. ENVTL. L.J. 461, 465 (2008) (citing *San Francisco Baykeeper v. Whitman*, 297 F.3d 877, 885-86 (9th Cir. 2002); *see also* *Oil, Chemical & Atomic Workers Union v. Occupational Safety and Health Administration*, 145 F.3d 120, 124 (3rd Cir. 2008) (refusing to compel agency action under section 706(1) where there was no “inaction that is either contrary to a specific Congressional mandate, in violation of a specific court order, or unduly transgressive of the agency’s own tentative deadlines”).

¹³⁷ Lisa Schultz Bressman, *Judicial Review of Agency Inaction: An Arbitrariness Approach*, 79 N.Y.U. L. REV. 1657 (2004) (arguing that “[a]n agency’s decision about how to allocate its resources among competing priorities is at the core of the policymaking discretion that the executive branch

There is a second option, on the other hand, that would provide the industry an opportunity for relief. Under section 553(e) of the APA, Medicaid physicians may petition CMS to finalize its 1998 rule and under section 555(e) of the APA, CMS is required to give prompt notice of its decision.¹³⁸ One of two scenarios would then play out. First, CMS could agree with the petition and finalize the rule. That is obviously the best-case scenario. The other, and more likely situation, is for CMS to deny the petition. In this case, the Medicaid physicians could challenge CMS's denial.

The courts' scope of review, however, is very narrow and limited to ensuring that the agency has adequately explained the relevant facts and policy concerns it relied on in making the decision, and that the facts have some basis in the record.¹³⁹ Regardless, this would engage CMS in a cost-effective way. Additionally, it may benefit Medicaid physicians who are facing FCA charges stemming from the Medicaid Stark law in court. Filing a petition will force CMS to actively decide whether or not to issue a final rule. Forcing CMS to be actively engaged may provide sufficient weight for the court to stay or dismiss the case under the primary jurisdiction doctrine.

C. Recommendations to the Courts

Over two hundred years ago, Chief Justice Marshall unequivocally stated "it is emphatically the province and duty of the judicial to say what the law is."¹⁴⁰ This statement, however, has been qualified by the rise of our current administrative state. Due to the ever-increasing complexity of the administrative framework, agencies must resolve statutory ambiguities in a uniform and workable manner.¹⁴¹ Congress and the courts recognize that agencies possess special knowledge and expertise that are suited for resolving these ambiguities. This Article highlights the need for an agency to promulgate regulations to ensure clarity and uniformity for its regulated beneficiaries in the face of a complex and ambiguous regulatory framework.

of the government and any administrative agency must have.); *see also* Biber, *supra* note 136 at 472 (noting that courts afford agencies a varying level of deference because a court should not "substitute its discretion for that of an administrative agency and thus exercise administrative duties") (internal citations omitted).

¹³⁸ 5 U.S.C. § 555(e) (providing that an agency is required to give "prompt notice . . . of [a] denial . . . of a . . . petition . . . made in connection with any agency proceeding . . . [and] the notice shall be accompanied by a brief statement of the grounds for denial.").

¹³⁹ *See* Massachusetts v. E.P.A., 549 U.S. 497, 527 (2007) (explaining that the scope of review for an agency's denial of a petition is narrow and that an agency has broad discretion to choose how best to marshal its limited resources).

¹⁴⁰ *Marbury v. Madison*, 5 U.S. 137, 177 (1803).

¹⁴¹ *See* Liu, *supra* note 108, 287 n. 3 (explaining that "Congress is presumed to delegate" agencies the authority to resolve ambiguities in statutory meaning); *Delegation and Individual Liberties*, *supra* note 108 (stating that the Supreme Court "has long recognized that administration of the law requires exercise of discretion, and that 'in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives.'");

CMS's failure to finalize its 1998 proposed rule has opened the door for courts' inconsistent handling of the Medicaid Stark law and the FCA.¹⁴² For example, the four district court cases would have had different outcomes if they had fallen in a jurisdiction that had already rejected the implied false certification theory. In addition, the costs associated with challenging an FCA claim and the likelihood of settlement limited the judiciary's ability to resolve the factual issues that would have prevented the outcome of the four district court cases.

This Article recommends that courts should apply the primary jurisdiction doctrine to either stay or dismiss these cases until CMS finalizes the 1998 proposed rule. The primary jurisdiction doctrine allows courts to use their prudential discretion to defer an issue to the expertise of administrative agency to, among other things, ensure uniformity in the law.¹⁴³ Staying or dismissing these cases could place additional pressure on CMS to finalize its 1998 rule to ensure that a uniform regulatory framework is established.¹⁴⁴

CONCLUSION

The issues presented in this Article highlight the need for clarity and uniformity within the regulatory framework of the SSA. CMS's failure to finalize its 1998 proposed rule has allowed courts to create inconsistent case law at the expense of Medicaid physicians. In addition, the use of the FCA to sanction self-referring Medicaid physicians is contrary to congressional intent. Congress did not intend to prohibit Medicaid physicians from making self-referrals the same way it did to Medicare physicians. Instead, Congress intended to extend the impact of the Medicare Stark law by prohibiting the federal government from making certain payments to the States. Moreover, Congress did not intend to create a private right of action under the Stark Laws.

These issues presented in this Article should be addressed by CMS and not by the judiciary. The judiciary's contribution to this body of law has resulted in numerous problems, which demonstrate that the judiciary is not the appropriate body to resolve these issues.¹⁴⁵ Instead, CMS, the entity charged with the oversight of the healthcare industry; the entity with the specialized knowledge and expertise to create a navigable and uniform regulatory framework; and the entity that already begun the rulemaking process is the entity that should be required to resolve this issue to best line with congressional intent.

¹⁴² See Matthew, *supra* note 37, at 545 ("The reasons various courts have approved or declined to find FCA liability . . . cannot be reconciled and therefore yield no clear instruction for future conduct.").

¹⁴³ See Aaron J. Lockwood, *The Primary Jurisdiction Doctrine: Competing Standards of Appellate Review*, 64 WASH. & LEE L. REV. 707 (2007) (explaining that the doctrine prudently allows administrative agencies to utilize their expertise and resolve critical issues); see also *United States v. W. Pac. R.R. Co.*, 352 U.S. 59 (1956) (recognizing that the doctrine has "no fixed formula," but is applied on a case-by-case basis).

¹⁴⁴ See Matthew, *supra* note 37, at 533 (arguing that "no court should entertain a tainted-claims case until after [the government] has first exercised primary jurisdiction under the . . . administrative provisions of the prevailing antifraud laws.").

¹⁴⁵ See *supra* Part II.

In conclusion, CMS should finalize its 1998 rule. Medicaid physicians, in order to initiate the rulemaking process, should petition CMS to finalize its rule. Finally, the judiciary should use its prudential discretion to either stay or dismiss any Medicaid Stark law case under the primary jurisdiction doctrine and until CMS finalizes the rule.