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HEALTH LAW & POLICY BRIEF
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Letter from the Editors

Dear Reader:

On behalf of the Editorial Board and staff, we proudly present Volume 10, Issue 1 of the *Health Law & Policy Brief* (HLPB). HLPB is an online publication run by law students at American University Washington College of Law (WCL). Since its formation in 2007, HLPB has published articles on a wide array of cutting-edge topics in the areas of health law, disability law, and food and drug law. Such topics include international and domestic issues of health care compliance, fraud and abuse enforcement, health insurance payment and reimbursement issues, intellectual property issues, international human rights issues, FDA initiatives and policies, and a host of other matters. HLPB also maintains a blog on current health law issues which can be found on our website at www.healthlawpolicy.org. Furthermore, each year, HLPB organizes an original symposium on an emerging health law topic. At this year's symposium in November 2015, distinguished speakers and moderators discussed the benefits and challenges of expanding the use of telemedicine and mHealth devices.

This issue features two timely articles. Our first author, Michael Grimes, analyzes how the federal government and whistleblowers have used the False Claims Act as a vehicle for alleged violations of the Medicaid Stark Law. He criticizes courts that have accepted this trend, argues that it conflicts with congressional intent, and encourages CMS or Congress to take corrective action.

Our second author, Charlie McKiver, calls attention to Missouri's failure to create a Prescription Drug Monitoring Program (PDMP), which would likely curb the state's high rates of opioid abuse. She explains that forty-nine out of fifty states have passed effective and legally valid PDMPs; Missouri legislators cannot claim that a PDMP would violate state or federal privacy regulations. Both articles are timely and important to current health law and policy. We would like to thank our authors for their hard work and cooperation.

We would also like to thank HLPB's articles editors and staff members who worked diligently on these articles, the blog, and our programming throughout the year. They are greatly appreciated and should be proud of their work.

For questions or information about the *Health Law & Policy Brief*, or for questions on how to subscribe to our electronic publication, please visit our website at www.healthlawpolicy.org.

Sincerely,
Mohammad and Kate

Mohammad H. Mesbahi
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A Stark Contrast To Congressional Intent

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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 relators[6] 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

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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 purposes[10] 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

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[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]

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[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]

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[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-medicaid-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

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[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 domingo 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]

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[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 (3rd 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

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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.

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[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

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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

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[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]

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[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

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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 form 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

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[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., *s*upra 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 funding[98] 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]

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[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'

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[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

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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.

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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 form claims resulting form 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

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[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.

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[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. Frist, 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.

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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 road 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.

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[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.

"Patient Privacy": The Illusory Barrier To Fixing Missouri's Opioid Overdose Problem

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INTRODUCTION

For much of the twentieth century, doctors only recognized pain as a symptom, never as an illness in itself.[1] As a result, doctors prescribed opioids, such as morphine and oxycodone, to treat short-term pain, but not to treat chronic pain.[2] Then, in the 1970s, medical professionals became more interested in managing pain and they began to view chronic pain as an illness in itself.[3] Although perceptions of chronic pain changed, the prescription drugs available to treat this illness did not, and doctors remained hesitant to treat chronic pain with highly addictive opioids.[4]

However, things changed in 1996 when pharmaceutical company Purdue Frederick obtained FDA approval for OxyContin, a time-release, less addictive oxycodone pill intended to treat chronic pain.[5] Purdue Frederick marketed OxyContin as "difficult to abuse," in an effort to assuage doctors' fears.[6] Due to this marketing, prescriptions of opioids quickly skyrocketed, but unfortunately, so did accidental opioid overdoses.[7]

Despite Purdue Frederick's claims, OxyContin (and other opioid analgesics) was actually highly susceptible to abuse because it could be "crushed, then swallowed, snorted, or injected for a powerful high."[8] Several states and individuals sued Purdue Frederick for misbranding OxyContin as a non-addictive drug.[9] The company ultimately pled guilty to a felony charge of misbranding and paid over $600 million in fines.[10] But no fine could remedy the destruction caused by the drug and the nation is still burdened by opioid abuse.

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[1] Ian Frazier, *The Antidote: Can Staten Island's Middle-Class Neighborhoods Defeat An Overdose Epidemic?*, New Yorker (Sept. 8, 2014), http://www.newyorker.com/magazine/2014/09/08/antidote.

[2] *Id.*; *see also* Chronic Pain: Symptoms, Diagnosis & Treatment, 6 NIH Medline Plus 1, 5-6 (2011), http://www.nlm.nih.gov/medlineplus/magazine/issues/spring11/articles/spring11pg5-6.html (explaining that short-term pain lasts no longer than twelve weeks and occurs during recovery from an injury or procedure or during the progression of terminal illness, while chronic pain is "any pain lasting more than 12 weeks").

[3] Frazier, *supra* note 1.

[4] *See A Nation in Pain: Focusing On U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain* 1, 4, Express Scripts Lab (Dec. 2014), http://lab.express-scripts.com/publications/a-nation-in-pain (explaining that doctors were reluctant to prescribe opioids because it is easy for patients to become addicted to them, as the body can build up a tolerance to opioid drugs and such drugs do not have a maximum clinically safe dosage limit) (hereinafter *A Nation in Pain*).

[5] Frazier, *supra* note 1.

[6] *Id.*

[7] *See* Alexandra Sifferlin, *The Problem with Treating Pain in America*, Time (Jan. 12, 2015), http://time.com/3663907/treating-pain-opioids-painkillers/ (explaining that the number of opioid prescriptions for pain has almost tripled, from 76 million to 219 million between 1991-2011, and the number of hospitalizations and deaths related to opioid addiction has also increased dramatically).

[8] Frazier, *supra* note 1.

[9] *Id.*

[10] *Id.*; Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html?_r=0.

Prescription opioid overdose death rates quadrupled from 1999-2013.[11] During this period, almost fifty Americans died from prescription drug overdoses daily.[12] Today, Americans make up less than 5% of the world's population, but consume more than 80% of the world's opiate supply.[13] Opioid abuse has also imposed significant costs on the American economy.[14] Fortunately, the United States recently experienced the first reduction in opioid overdose deaths in over a decade.[15] And some states, like Florida, have seen a dramatic decrease in overdose deaths, largely because of their initiatives aimed at curtailing opioid overprescribing.[16]

The most successful of these initiatives have been Prescription Drug Monitoring Programs (PDMPs), which are electronic databases that monitor opioid prescriptions. Because PDMPs have proven to both curb medically unnecessary opioid prescriptions and reduce opioid mortality, all but one state legislature has enacted legislation to create a PDMP.[17] The lone holdout is the state of Missouri. Although residents of seven neighboring states with PDMPs travel to Missouri to procure opioids and Missouri has become known as "America's Drug Store," its legislature has refused to establish a PDMP.[18] Conservative lawmakers in Missouri cite patient privacy concerns for their past refusal to pass a PDMP. In March of 2015, the state's senate passed a bill authorizing a PDMP, but it contained numerous measures designed to protect patient privacy. The Missouri senate bill was ultimately not enacted into law, but this Article will argue that Missouri legislators' concerns about patient privacy are not compelling.

This Article will explain why the Missouri state legislature should pass a statute to authorize a PDMP. It will then outline why drafting a robust and effective PDMP will not violate the Constitution, or federal and state privacy regulations.

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[11] *Injury Prevention and Control: Prescription Drug Overdose*, Centers for Disease Control and Prevention, http://www.cdc.gov/drugoverdose/data/index.html.

[12] *Id.*

[13] *A Nation in Pain*, *supra* note 4 at 4.

[14] *Id.* (including $42 billion in lost productivity, $8.2 billion in increased criminal justice costs, $2.2 billion for drug abuse treatment, and $944 million in medical complications).

[15] Margaret Warner, Holly Hedegaard, & Li-Hui Chen, *Trends in Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999-2012*, Centers for Disease Control and Prevention (Dec. 2014), http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning.htm (reporting a 5% decline in opioid-analgesic overdose deaths between 2011 and 2012).

[16] *See* Hal Johnson et al., *Decline in Drug Overdose Deaths After State Policy Changes*, Centers for Disease Control and Prevention, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm (stating that overdose deaths from oxycodone have decreased 52.1%, while overall death rates for prescription drugs have only decreased 23.2%).

[17] Jeffrey Levi et al., *Prescription Drug Abuse: Strategies to Stop the Epidemic 2013* 1, 16, Trust for America's Health, (Oct. 2013), http://healthyamericans.org/reports/drugabuse2013/TFAH2013RxDrugAbuseRpt12_no_embargo.pdf.

[18] Alan Schwarz, *Missouri Alone in Resisting Prescription Drug Database*, N.Y. Times (July 20, 2014), http://www.nytimes.com/2014/07/21/us/missouri-alone-in-resisting-prescription-drug-database.html?_r=0.

I. PRESCRIPTION DRUG MONITORING PROGRAMS: THE BEST APPROACH FOR LOWERING OPIOID OVERDOSE RATES

In response to increased opioid abuse and overdoses, states have implemented various regulatory initiatives, including anti-doctor-shopping laws, increased Medicaid reimbursement for substance abuse treatment, Good Samaritan laws, Naloxone Access laws, physical exam and ID requirements for opioid prescriptions, Prescription Drug Monitoring Programs, and Pharmacy Lock-in Programs.[19] Many of these initiatives try to prevent abusers from obtaining multiple prescriptions from different providers. Two of the most popular initiatives that impact doctor prescribing and patient access to opioids are anti-doctor shopping laws and Prescription Drug Monitoring Programs.[20]

Every state in America has an anti-doctor-shopping law, requiring a patient to disclose his or her prescription drug history before receiving another prescription from a different provider.[21] Anti-doctor shopping laws often deter patients from seeking medically unnecessary opioids from multiple providers.[22] However, once the patient discloses the information, the provider has the discretion as to whether to prescribe additional opioids or report suspected abuse. Such laws have a limited impact on reckless physician prescribing practices. For this reason, every state, except Missouri, also has a Prescription Drug Monitoring Program.[23]

A PDMP is an electronic database, established and operated by the state, which monitors the prescription and dispensation of controlled substances.[24] Legislation authorizing a PDMP often addresses which regulatory actor[s] will create the database and collect and compile the information, as well as the permissible uses of that information.[25] A state must also allocate funds for the PDMP, although it can obtain supplemental funds from the U.S. Department of Justice (DOJ) and the Substance Abuse and Mental Health Services Administration (SAMHSA).[26]

While states' PDMPs vary, they all provide state regulatory bodies, law enforcement officials, or pharmacists and physicians access to information that will hopefully identify potential opioid abusers.[27] At least sixteen of the forty-nine states require physicians

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[19] Levi et al., *supra* note 17, at 14-15.

[20] *Id.* at 16.

[21] *Id.* at 21.

[22] *Id.*

[23] *Id.* at 16.

[24] *Id.* at 18.

[25] *See, e.g.*, Fla. Stat. § 893.055 (2015).

[26] *See* Levi et al., *supra* note 17, at 38 (detailing SAMHSA's funding of the Health IT Project, which provided states with grants to use health information technology to increase access to PDMP data); Laxmaiah Manchikanti et al., *Evolution of the National All Schedules Prescription Electronic Reporting Act: A Public Law for Balancing Treatment of Pain and Drug Abuse and Diversion*, 8 Pain Physician 4, 335, 336 (2005) (explaining that DOJ manages the Harold Rogers Prescription Drug Monitoring Program, which makes $11 million available to states to monitor prescription drugs and scheduled listed chemical products).

[27] Levi et al., *supra* note 17, at 20 (explaining PDMPs help to identify many sources of prescription drug abuse such as prescription fraud, forgeries, doctor shopping, and improper prescribing and dispensing).

and/ or pharmacists to check a patient's history in a PDMP before enabling that patient to obtain additional opioids.[28] PDMPs are particularly effective because they target numerous causal pathways that lead to opioid overdoses — they curb improper doctor prescribing and patient access to opioids, prevent diversion of drugs, and isolate opioid addicts for treatment.[29]

Opioid overdose deaths have been declining since 2011.[30] While PDMPs are not possibly the sole cause of this decrease, they clearly have some positive effect.[31] PDMPs have been particularly beneficial in Florida and Tennessee. After Tennessee enacted it's PDMP in 2013, the state's number of "high utilizers" of opioids (those most at risk for opioid overdose) declined by forty-seven percent.[32] Florida, which boasted ninety-eight of the one hundred physicians dispensing the highest volumes of oxycodone in the country in 2010, experienced similar success.[33] After establishing a PDMP in 2011, Florida closed down many of these physicians' "pill mills" and as a result, saw a decline of more than seventeen percent in the number of oxycodone overdose deaths.[34]

While PDMPs vary, they are more effective when prescribers, pharmacists, and law enforcement have more access to program data.[35] When such actors have access to PDMPs, they can better prevent opioid abuse and overdoses.

Brandeis University's Prescription Drug Monitoring Program Center of Excellence[36] has drafted a Model Act, which suggests best practices for PDMPs, provisions of which are endorsed by the U.S. Department of Health and Human Services (HHS).[37] The Model Act provides that a prescriber or pharmacist should be able to view a

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[28] *Id.* at 20.

[29] *Id.* at 35.

[30] *See* Johnson et al, *supra* note 16, at 570 (reporting a 16.7% decline in drug overdose deaths between 2010 and 2012).

[31] *See id.* (acknowledging that it is impossible for the CDC to determine which initiatives were most responsible for the decline in drug overdose deaths).

[32] *A Nation in Pain*, *supra* note 4, at 21.

[33] Johnson et al., *supra* note 16, at 569.

[34] *Id.*

[35] *See id.* at 570 (explaining that providers accessed Florida's PDMP 92 times from September through December of 2011, which resulted in a decrease in opioid overdoses).

[36] *See About the PDMP Center of Excellence, Brandeis University*, http://pdmpexcellence.org/about (explaining that it is "funded by grants from the U.S. Department of Justice and Bureau of Justice Assistance…[, and] collaborates with a wide variety of PDMP stakeholders, including federal and state governments and agencies, universities, health departments, and medical and pharmacy boards").

[37] *See HHS takes strong steps to address opioid-related overdose, death and dependence*, U.S. Department of Health and Human Services (Mar. 26, 2015), http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html (hereinafter HHS Press Release) (explaining that the HHS Secretary believes PDMP effectiveness will increase as "states adopt more evidence-based PDMP practices such as collecting data for all controlled substances, proactive reporting to physicians and pharmacists, interstate data sharing, and integration with other health IT systems to improve provider use"); *see also* Susan Chaityn Lebovits, *Heller Team Helps Fight Prescription Drug Abuse*, BrandeisNOW (Mar. 5, 2012), http://brandeis.edu/now/2012/march/drugs.html.

patient's full record in the PDMP, before prescribing or dispensing additional opioids to the patient.[38] Such access helps the prescriber or pharmacist make the (not always clear) distinction between medically necessary treatment and troubling opioid use.[39] After viewing the patient's record in the PDMP, the prescriber or pharmacist may also need to obtain additional information from that patient. For example, a patient with multiple opioid prescriptions — might be abusing those drugs or might be struggling to consistently access medical care and needs help managing pain stemming from multiple conditions.[40] But by accessing the PDMP, a prescriber or pharmacist can at least start the conversation.

The Model Act also provides that each state's PDMP should be interoperable with other PDMPs and electronic health record databases throughout the country.[41] In addition, the Model Act makes a PDMP accessible to medical providers' licensing boards, so they can properly investigate provider misconduct.[42] Not all states have adopted these updates in the Model Act, but as political pressure intensifies to curb opioid overdoses, more states should make these legislative changes to craft more effective PDMPs.

II. WHAT'S THE DEAL, MISSOURI?

As forty-nine states look for ways to improve the effectiveness of their established PDMPs, the Missouri legislature still refuses to authorize a PDMP.[43] Additionally, the Missouri legislature has only adopted three countermeasures to reduce opioid overdose while most states have adopted six or more.[44] Because of the legislature's refusal to act, in 2010, Missouri had the seventh highest prescription drug overdose mortality rate in the country.[45] And since 1999, drug overdose deaths in the state have tripled.[46]

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[38] *Prescription Drug Epidemic: Hearing Before the S. Subcomm. on Crime & Terrorism*, 112th Cong. 4 (2011) (statement of John L. Eadie, Director, Prescription Monitoring Program Center of Excellence) (hereinafter *Prescription Drug Epidemic*).

[39] *See* Christopher A. Griggs, et al., *Prescription Drug Monitoring Programs: Examining Limitations and Future Approaches*, 16 West J. Emerg. Med. 67, 68 (2015), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4307729/ (detailing current challenges in evaluating patient data and proposing how to make PDMPs more effective).

[40] *Id.*

[41] *See Prescription Drug Epidemic, supra* note 38, at 5; see also Levi et al., *supra* note 17, at 37 (explaining that for a PDMP to be effective, "healthcare providers and law enforcement agencies [must] be able to share information across state and jurisdictional boundaries").

[42] *Prescription Drug Epidemic*, *supra* note 38, at 7.

[43] *See* Schwarz, *supra* note 18 (explaining that although many states have a PDMP, the legislation varies as to who has access to the database).

[44] *See* Levi et al, *supra* note 17, at 16-17 (explaining that Missouri (1) requires a patient to submit to a physical exam before obtaining a prescription for opioid analgesics; (2) criminalizes the non-disclosure of existing opioid prescriptions to a new provider; and (3) "locks in" any Medicaid beneficiary suspected of misusing controlled substances with a single provider and pharmacist).

[45] *Id.* at 12. This paper argues that any state benefits from establishing a PDMP that can serve as a central repository of patients' prescriptions for opioids. However, the paper recognizes that other factors, including age, social structure, and poverty— may affect a given state's prescription drug overdose rates. Those other factors are compelling, but beyond the scope of this Article.

[46] *Id.*

Residents of neighboring states have even started traveling to Missouri to fill their opioid prescriptions.[47]

The lack of a PDMP in Missouri has even brought national attention. In 2012, the Director of the White House's Office of National Drug Control Policy visited Missouri and urged the state legislature to establish a Prescription Drug Monitoring Program.[48] Some lawmakers have proposed legislation to create a PDMP, but conservatives have struck them down,[49] citing patient privacy concerns.[50] However, Missourians are growing tired of the legislature's excuses. For example, in February 2015, activists from the Missouri Network for Opiate Reform and Recovery carried a coffin filled with 1,000 pill bottles bearing the names of victims of fatal overdoses to the state capitol building, to build political pressure.[51]

On April 2, 2015, the state senate passed a bill that would authorize a Prescription Drug Monitoring Program.[52] The legislation died in the Missouri House Select Committee on Insurance,[53] but even if it passed, the resulting PDMP would have been largely ineffective. The proposed bill would have authorized the Missouri Department of Health and Senior Services to establish and run a Prescription Drug Monitoring Program.[54] It would have permitted any provider to report prescriptions for opioids to the database. In contrast, it would have *required* every pharmacist to report every filled prescription to the database.[55] After submitting information to the database, a pharmacist would have received a response from the department, indicating whether the pharmacist should have any concern about giving the controlled substance to the patient.[56] If the agency indicated any reason for concern, however, the pharmacist would have been permitted

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[47] Schwarz, *supra* note 18.

[48] Cameron Hardesty, *Director Kerlikowske Visits Missouri; Urges Adoption of Prescription Drug Monitoring Program*, The White House (Aug. 17, 2012 11:17AM), https://www.whitehouse.gov/blog/2012/08/17/director-kerlikowske-visits-missouri-urges-adoption-prescription-drug-monitoring-pro.

[49] Id.

[50] *See, e.g.,* Kyle Loethen, *Missouri Senate Passes Prescription Drug Monitoring*, Missourinet (Apr. 6, 2015), http://www.missourinet.com/2015/04/06/missouri-senate-passes-prescription-drug-monitoring-program/ (citing one senator's disapproval of systems that collect personal data from individuals who have not committed crimes).

[51] Grant Bissell, *Coffin with Pill Bottles Going to the Missouri Capitol*, KSDK (Feb. 23, 2015), http://www.ksdk.com/story/news/politics/2015/02/24/coffin-with-pill-bottles-going-to-mo-capitol/23922245/.

[52] S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015).

[53] *See Current Bill Summary: S.B. 63*, Missouri Senate, http://www.senate.mo.gov/15info/BTS_Web/Bill.aspx?SessionType=R&BillID=156 (last visited Jan. 3, 2016) (showing that the last action on the bill was a third reading in the House on May 15, 2015).

[54] *See* S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015) (proposing that the agency would use the system to monitor all schedule II-IV controlled substances licensed and prescribed in the state).

[55] *Id.*

[56] *Id.* (stating that dispenser will obtain a response from department after transferring information to the database, but not explaining how long it will take to receive such a response).

to use his or her judgment as to whether to prescribe the drug.[57] The proposed bill also would have imposed numerous regulatory prohibitions on access to the database: it would have prohibited providers and pharmacists from accessing the data[58]; would have disallowed combining information from the database with patient Electronic Health Records data[59]; and would have banned the entry of information from the state PDMP into the national PDMP.[60]

Although the proposed bill represented a huge step forward for the Missouri Senate, it did not follow the PDMP Model Act and if passed, it would have created an ineffective PDMP.[61] The bill did not mandate that providers actually use the database, which researchers believe is a key attribute of a successful PDMP.[62] Furthermore, denying prescribers and dispensers access to the database would have undermined these professionals' ability to treat their patients, and could have resulted in the unwarranted denial of opioids to patients who need them.[63] The proposed bill also would have banned interoperability between the Missouri database and Electronic Health Records[64] although research suggests that information sharing between EHRs and PDMPs improves physicians' prescribing decisions.[65] Finally, Missouri's proposed bill would have prevented the PDMP from sharing information with the national database, which would have combated interstate doctor shopping.[66]

III. IS PRIVACY REALLY A BARRIER?

Missouri's proposed bill would have restricted access to the PDMP primarily to "take doctors out of the equation [and not] make them into policemen."[67] However, public health surveillance activities, such as PDMPs, are not a new form of governance and

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[57] *Id.* (stating that the department will express concern but that it is up to the dispenser to make a final judgment).

[58] *Id.* (noting that "dispensers and prescribers are not required to access the database and they are only to input data, not access information").

[59] *Id.* (noting that dispenser and prescriber data will not be mixed with other databases").

[60] *Id.* (noting that the information will not be linked with other state databases into a national database).

[61] *See Prescription Drug Epidemic*, *supra* note 39, at 4 (recommending several features for a PDMP, which Missouri's proposed bill did not include).

[62] *See, e.g.,* Levi et al., *supra* note 17, at 16 (giving greater esteem to state laws that mandate PDMP use).

[63] *See Prescription Drug Epidemic*, *supra* note 39, at 5 (stating that "PDMPs [should] provide prescription histories to prescribers so they can make clinically sound decisions prior to issuing prescriptions for controlled substances and can avoid being duped by doctor shoppers").

[64] S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015)

[65] See Levi et al., *supra* note 17, at 38 (noting that combining electronic health record data and PDMP data improves the quality of prescription drug information available and allows rapid access to such information).

[66] *Id.* at 37 (arguing that shared information benefits state health systems and that 44 states share PDMP data with other states with 19 states requiring individuals to request the state obtain information from another state).

[67] Bissell, *supra* note 52.

have been used by public health departments as an effective means to combat both infectious and chronic disease.[68] Furthermore, courts have resoundingly upheld the legality of surveillance by public health agencies, pharmacists, and providers because patients feel little harm.[69] These public health activities, however, have not been without controversy. Individuals with the same privacy concerns as the Missouri legislature have unsuccessfully challenged public health surveillance activities under both the Due Process Clause and the Health Insurance Portability and Accountability Act.[70]

Missouri legislators opposing establishment of a PDMP have posited that such programs abridge individuals' freedoms.[71] Such liberty concerns are generally analyzed under the Due Process Clause.[72] However, the Supreme Court resolved such privacy arguments in 1977.[73] In *Whalen v. Roe*, the Supreme Court held that the Due Process Clause protected an individual's right to privacy in his or her health information, but ultimately upheld the government's collection of health information so long as it was adequately secured.[74] In later decisions, courts interpreted *Whalen* as conferring a limited right to privacy.[75] Courts now evaluate public health surveillance activities by balancing an individual's privacy interest against the government's interest in collecting the

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[68] *See, e.g.*, Lawrence O. Gostin & Lindsey F. Wiley, Public Health Law: Power, Duty & Restraint— Chapter 9: Surveillance & Public Health Law 28 (forthcoming 2016) (hereinafter Gostin & Wiley, *Surveillance & Public Health Law*) (explaining that in 2006, the New York City Board of Health responded to a diabetes epidemic by requiring laboratories (but not physicians) to report hemoglobin AIC test results to the city).

[69] *See* Lawrence O. Gostin, *"Police" Powers and Public Health Paternalism: HIV and Diabetes Surveillance*, 37 Hastings Cent. Rep. 9, 10 (2007) (arguing that patients have limited ammunition in their arguments over the privacy aspects of public health data because of the many benefits that such disclosures can bring).

[70] *See, e.g., Whalen v. Roe*, 429 U.S. 589 (1977).

[71] *See, e.g.*, Loethen, *supra* note 50 (citing one state senator's argument that "whenever you take an innocent person's information and put it in a database[,] that takes away their liberty that takes away their freedoms").

[72] Loethen, *supra* note 50.

[73] See *Whalen*, 429 U.S. at 603-604 (upholding a New York statute that required prescriptions of Schedule II drugs to be prepared on an official form, which identified the patient's name and address).

[74] *See id.* at 601 (holding that the impact of the release of patient identification on their reputation and independence was not sufficient to constitute an invasion of their Fourteenth Amendment privacy rights).

[75] *See, e.g., Nixon v. Adm'r of Gen. Servs*., 433 U.S. 425, 457-459 (1977) (stating that when there is a government interest at stake, any disclosure of private matters must be weighed against the public interest); *Planned Parenthood v. Danforth*, 428 U.S. 52, 80 (1976) (advocating that recordkeeping and reporting mandates aimed at preserving the mother's health are permissible if they respect patient privacy); *Rasmussen v. S. Fla. Blood Serv., Inc.*, 500 So. 2d 533, 535 (Fla. 1987) (reaffirming the two privacy interests in Whalen, the individual interest in avoiding the dissemination of private matters and the interest in preserving independence in making important decisions).

data.[76] Since HHS has declared opioid abuse to be a national epidemic,[77] the Missouri government most likely has a compelling interest in authorizing a Prescription Drug Monitoring Program. Furthermore, patients feel little harm if information is only shared between medical providers and public health agencies.[78] Also, most authorizing legislation for PDMPs, including the Missouri Senate Bill[79], requires data collected by government agencies to be encrypted, which would limit the risk of privacy breaches and meet the adequate surveillance test enunciated in *Whalen*.[80]

It is clear, under the prevailing balancing test for evaluating public health surveillance, that Missouri's interest in opioid prescribing information would outweigh any invasion of patients' privacy and would justify the Missouri Senate's proposed PDMP legislation. Missouri's legislature could even pass more robust legislation, which would share the PDMP's information with providers, without violating health information privacy protections conferred by the Due Process Clause.

Opponents of PDMPs also argue that PDMPs violate privacy laws. However, the federal privacy law, the Health Insurance Portability and Accountability Act (HIPAA),[81] and Missouri's privacy regulations[82] both authorize protected health information to be authorized for patient treatment and public health surveillance purposes.

Upon passing HIPAA in 1996, Congress directed the Secretary of HHS to promulgate final regulations "governing standards with respect to the privacy of individually identifiable health information" within 42 months of the enactment of the Act.[83] In response, HHS published its final privacy rules in December of 2000.[84] The privacy regulations only

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[76] *See, e.g., United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 578 (3d Cir. 1980) (establishing the balancing factors to be considered when justifying whether to intrude on an individual's privacy: type of record requested; the information it does or may contain; potential harm resulting from nonconsensual disclosure; injury resulting from disclosure to the relationship in which the record was generated; adequacy of the safeguards to prevent disclosure; the urgency of need for access; and the existence of a statutory, public policy, or public interest justification for access).

[77] *See* HHS Press Release, *supra* note 37.

[78] *See* Gostin, *supra* note 69, at 10 (arguing that patients are not impacted by this intrusion on their privacy).

[79] S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015). (stating that "all communications and data transmitted [to and from the proposed PDMP] shall be encrypted").

[80] *See* Gostin & Wiley, *Surveillance & Public Health Law, supra* note 68, at 16 (explaining that the *Whalen* court determined that the state had adequate security measures in place, such as keeping computer tapes in a locked cabinet, operating the computer off-line to prevent unauthorized access, and disclosing data to only a limited number of officials).

[81] 45 C.F.R. § 164.502(a) (2014); 45 C.F.R. § 164.512(b) (2014); *see also* Richard Sobel, *The HIPAA Paradox: The Privacy Rule That's Not*, 37 Hastings Cent. Rep. 40, 40 (Aug. 2007) (explaining that the HIPAA Privacy Rule is not absolute, but rather, sets forth which disclosures are required and permitted).

[82] Mo. Code Regs. Ann. tit. 13, §§ 70-1.010 *et seq.* (2015).

[83] The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 264, 110 Stat. 2033, 104th Cong. (1996).

[84] 45 C.F.R. §§ 160, 164 (2000).

apply to "covered entities" (including doctors, pharmacists, and HMOs)[85], and prohibit these entities from disclosing "protected health information" (PHI)[86] without patient permission unless a regulatory exception applies. Covered entities, however, may share "de-identified information" and can sometimes permissively disclose PHI.[87] HIPAA authorizes permissive disclosure of PHI for "public health activities,"[88] and so, the creation of a public health surveillance system to monitor opioid prescriptions would be permitted under federal regulations. In the Final Rule, HHS explained that it permitted these exceptions because an individual's right to privacy is "not absolute."[89]

However, HIPAA is only a "floor" of legal protection over each individual's protected health information; any state may pass more restrictive legislation if it chooses.[90] Therefore, it is necessary to analyze whether a particular state's privacy laws would authorize a PDMP. Missouri has similar, but arguably stricter, privacy regulations in comparison to HIPAA.[91] Missouri mandates disclosure of contagious disease, firearm injuries, medication reactions, work-related injuries, and birth and death information; however, it does not have a broad authority for permissive disclosure of "public health activities."[92] The number of authorities for mandatory disclosure of PHI in the Missouri regulations is significant and reflects the notion that the state must overcome individuals' privacy concerns in order to address threats to public health. However, under the Missouri regulations, disclosure of PHI related to opioid prescriptions could not be disclosed to the

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[85] 45 C.F.R. § 160.103 (2000) (defining a "covered entity" as "(1) a "health plan; (2) a health care clearinghouses,; (3), a health care provider who transmit any health information in electronic form in connection with a transaction covered by . . . ." the" Act).

[86] 45 C.F.R. § 160.103 (defining protected health information as "is individually identifiable health information . . . [t]ransmitted or maintained . . . transmitted in any form or medium," but excluding educational and employment records... Health information must "[r]elate to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual").

[87] *See generally* 45 C.F.R. § 164.510 (2000) (listing the "Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required").

[88] 45 C.F.R. § 164.512(b) (allowing disclosure of PHI "without individual authorization to: (1) A public health authority authorized by law to collect . . . such information for purpose of preventing or controlling disease, injury, or disability, including . . . reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, . . . and public health interventions; . . . ").

[89] 45 C.F.R. § 160("It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed").

[90] Lawrence O. Gostin & Lindsay F. Wiley, *Public Health Law: Power, Duty, Restraint, Chapter 3: Public Health In the Constitutional Design*, 3 (forthcoming 2016) (explaining that HIPAA, similar to federal civil rights and consumer protection laws, achieves "floor preemption" because it only preempts state and local laws that fall short, however, states and localities are permitted to pass more robust laws if they choose).

[91] Mo. Code Regs. Ann. tit. 13, § 70-1.010 (2015).

[92] Mo. Code Regs. Ann. tit. 13, § 70-1.020(3)(B) ("The Department of Social Services, MO HealthNet Division shall provide information—1. To public health authorities to report contagious and reportable disease, including but not limited to . . . birth defects, cancer, or other information for public health purposes; 2. Reporting of certain types of wounds or other physical injuries…"). . . . ").

Missouri Department of Health and Senior Services under their mandatory disclosure authority, which is limited to specific public health surveillance purposes.[93]

However, both HIPAA and the Missouri privacy regulations permit disclosure of protected health information for "treatment" purposes. HIPAA provides that a covered entity (e.g., a physician or hospital) *may* disclose protected health information about an individual in order to treat the individual, and can consult with other health care providers about courses of treatment.[94] The Missouri regulations also permit the disclosure of PHI for treatment purposes in accordance with HIPAA.[95] The Missouri regulations provide an expansive definition of what "treatment" warrants PHI disclosure.[96]

Furthermore, the Missouri Senate Bill's proposed PDMP would not have violated HIPAA or the Missouri regulations, because it would have only required pharmacists and permitted providers to use the database for treatment purposes (e.g., deciding whether to fill prescriptions for opioids). If the Missouri legislature goes further and creates a PDMP following the Model Act, that would not violate HIPAA or the state's privacy regulations because the PDMP's central purpose would be to identify and treat patients who are addicted to opioids.[97]

CONCLUSION

The Missouri legislature's inability to pass a PDMP has contributed to increasing opioid overdose rates in both Missouri and surrounding states.[98] But as a late adopter of this public health measure, the state legislature also has a unique opportunity to build on evidence-based practices to craft a resoundingly effective PDMP. Unfortunately, the state senate passed a largely toothless bill that the house rejected, allegedly because of concerns with patient privacy.[99] But these concerns are unfounded, as the right to patient privacy is not absolute,[100] and even the most expansive PDMP legislation (e.g., the

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[93] *Id.*

[94] 45 C.F.R. § 164.501 (2000) (explaining that "disclosure of protected health information for treatment of any health care provider may include a provider sending a copy of an individual's medical record to a specialist who needs the information to treat the individual").

[95] Mo. Code Regs. Ann. tit. 13, § 70-1.020(4) ("The Department of Social Services . . . may disclose, at its discretion, a participant's protected health information to designated business associates in accordance with and as authorized by HIPAA . . . ").

[96] Mo. Code Regs. Ann. tit. 13, § 70-1.020(4)(B) ("Treatment of a Participant. Includes activities such as, providing, coordinating, or managing health care delivery and related services; consultation between providers relating to a participant; referral of a participant to another provider for health care; and necessary sharing of information through a health information network for treatment purposes . . . ").

[97] Levi et al., *supra* note 17, at 20 (explaining that by creating a PDMP and requiring providers and prescribers to use it, a state can prevent and treat opioid abuse).

[98] *Supra* notes 45-47 and accompanying text (discussing that Missouri has the seventh highest opioid mortality rate and that patients from contiguous states go to Missouri to purchase opioids).

[99] *See supra* notes 48-60 and accompanying text (evaluating the proposed bill).

[100] *See, e.g.*, Gostin, *supra* note 69, at 10 (arguing that "justice [does not require] government to leave people utterly alone, free to act in ways that cause severe disability and premature death").

PMP Model Act) does not violate the privacy protections afforded by the Constitution, HIPAA, and Missouri state regulations.[101]

Unfortunately, patient privacy protections are not the only barrier to passing authorizing legislation in Missouri; some of the state's conservative lawmakers also seem generally distasteful of people addicted to drugs.[102] However, such lawmakers should overcome such biases and join the national fight against opioid overdoses. Since Missouri does not have a PDMP, its legislature could and should adopt a PDMP similar to the PDMP envisioned in the Model Act.[103] The legislature must mandate, consistent with the Model Act, that both prescribers and pharmacists have full access to the database and must report each prescription written or dispensed to the database.[104] The Act should also permit interoperability with the state's electronic health records system and the national prescription monitoring database to help doctors better treat their patients and to combat interstate doctor shopping.[105] By adopting these measures, Missouri will see a significant reduction in opioid overdoses and could become a national leader in the fight against opioid overdose.

[101] *See supra* notes 67-95 and accompanying text.

[102] *See* Schwarz, *supra* note 18 (quoting Missouri Senator Robert Schaff, a leading opponent of creating a PDMP, in 2012: "if [drug abusers] overdose and kill themselves, it just removes them from the gene pool").

[103] *Prescription Drug Epidemic, supra* note 38, at 3-4.

[104] *Id.* at 4-5.

[105] *Id.* at 4.

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