
2016

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Caitlin Pardue

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Recommended Citation

Caitlin Pardue, *How Will I Know? An Auditing Privilege and Health Care Compliance*, 65 Emory L. Rev. 1139 (2016).

Available at: <https://scholarlycommons.law.emory.edu/elj/vol65/iss4/4>

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HOW WILL I KNOW? AN AUDITING PRIVILEGE AND HEALTH CARE COMPLIANCE[†]

ABSTRACT

The current complexities of the False Claims Act and the Affordable Care Act have impacted the rise of government enforcement of fraud and abuse laws within health care entities. Yet this rise in enforcement does not adequately address efforts focused on preventing unintentional violations from occurring. For this reason, the current health care regulation landscape calls for an additional strategy to reduce fraud and abuse violations: establishing a compliance audit privilege.

This Comment analyzes the peer review privilege established in the Patient Safety Quality Improvement Act of 2005 (PSQIA), which established a privilege for data collected to improve patient safety, and suggests that a compliance audit privilege fulfills a similar goal. Although there are several differences between patient safety data and compliance audit data, this Comment argues that such differences should not preclude Congress from enacting a compliance audit privilege because compliance and patient safety have compelling similarities. The PSQIA and compliance audits both aim to improve quality and compliance through proactive efforts collecting data, performing ongoing root cause analyses, and encouraging a culture of openness within a health care entity. Because of these similarities, the benefits seen from the PSQIA privilege are likely to be experienced in improved compliance if a compliance audit privilege is recognized.

[†] This Comment received the 2015 Mary Laura “Chee” Davis Award for Writing Excellence.

INTRODUCTION

Health care in America is in a state of transformation. The rise of technology is transforming the doctor–patient relationship,¹ the Affordable Care Act is transforming the way health care is provided and paid for,² and the focus on quality of care is transforming the way health care is measured.³ However, throughout this time of change, the desire to create an efficient, affordable, and effective health care system has remained constant.

One way to improve efficiency, affordability, and quality in our health care system is to ensure all health care entities⁴ have robust compliance programs. Compliance with federal regulations promotes efficiency and affordability because it protects against wasteful or fraudulent spending; compliance also improves quality by streamlining disease management systems, reducing medical malpractice incidents, and improving data privacy.⁵ One crucial component to compliance programs is compliance audits; auditing provides a comprehensive review of a health care entity’s compliance program, including evaluation of compliance policies, identifying and managing risk, and recognizing areas for additional personnel training.⁶

However, the recent rise of False Claims Act (FCA) enforcement has stifled efforts to promote robust internal compliance audits because health care entities fear these types of audits are discoverable in potential future litigation.⁷ This Comment argues that the current lack of privilege for compliance audits creates an unnecessary barrier to improving health care costs and quality. Because the predicted quality improvements facilitated by a privilege outweigh

¹ Jen Hyatt, *Tech Will Transform the Doctor-Patient Relationship*, HEALTH SERV. J. (July 14, 2014), <http://www.hsj.co.uk/home/innovation-and-efficiency/innovation-network/tech-will-transform-the-doctor-patient-relationship/5072505.article>.

² *Key Features of the Affordable Care Act by Year*, U.S. DEPT. HEALTH & HUM. SERVS., <http://www.hhs.gov/healthcare/facts/timeline/timeline-text.html> (last visited Aug. 13, 2015).

³ See Max Nisen, *How One of America’s Largest Health-Care Providers Prepares for Obamacare and the Future*, BUS. INSIDER (Sept. 18, 2013, 1:38 PM), <http://www.businessinsider.com/how-american-health-care-is-changing-2013-9>.

⁴ For the purposes of this Comment, a health care entity means “a hospital; an entity that provides health care services . . . [or] a professional society . . . that engages in professional review activity . . . for the purpose of furthering quality health care.” 45 C.F.R. 60.3 (2015).

⁵ See D. Scott Jones, *Quantifying Compliance and Quality: Understanding the Economic Impact of Inadequate Care*, 10 J. HEALTH CARE COMPLIANCE, May–June 2008, at 41, 41; *Health Information Privacy and Security: A 10 Step Plan*, HEALTHIT.GOV, <http://www.healthit.gov/providers-professionals/ehr-privacy-security/10-step-plan>.

⁶ See *infra* Part II.A.

⁷ See *infra* Part II.B.

the need for the information to be discoverable in potential future litigation, Congress should legislate a privilege for compliance auditing.

Health care entities have much to fear in potential future litigation due to the government's zealous enforcement of the FCA.⁸ The FCA was enacted after the Civil War and creates liability for anyone who submits a fraudulent payment claim to the government.⁹ Since that time, the FCA has grown in complexity and has been utilized to enforce multi-million dollar penalties and settlements against health care entities for submitting such fraudulent payment claims.¹⁰

For most FCA violations, actual knowledge of a violation is not required to establish liability.¹¹ While intentional fraud continues to occur, the government¹² is also aggressively enforcing the FCA against unintentional mistakes that result in FCA liability.¹³ As a result, a hospital entity may be subjected to enormous penalties for a violation it had no knowledge of, regardless of good faith efforts to comply with the complex array of regulations.¹⁴

Unintentional violations are distinctly different from intentional fraud because unintentional violations are often the result of negligence, confusion in

⁸ See *infra* Part I.D.

⁹ See, e.g., John M. Degnan & Sally A. Scoggin, *Avoiding Health Care Qui Tam Actions*, 74 DEF. COUNS. J. 385, 385-86 (2007) (discussing FCA enforcement in health care actions).

¹⁰ See, e.g., Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 124 & n.2 (2001) (noting that "federal health care programs are governed by an enormous number of legal provisions, spanning hundreds of thousands of pages"). "[The] recent proliferation of fraud cases can be blamed on [the] fact 'that healthcare regulations have just become too complicated to understand.'" *Id.* at 124 n.2 (quoting Uwe E. Reinhardt, Opinion, *Medicare Can Turn Anyone into a Crook*, WALL ST. J. (Jan. 21, 2000, 12:01 AM), <http://www.wsj.com/articles/SB948408802553884631>).

¹¹ See CHRISTINA W. FLEPS, HEALTH CARE FRAUD AND ABUSE COMPLIANCE MANUAL § 2:1, Westlaw 2015 WL 9482445 (C.C.H.) (database updated Dec. 2015) (citing Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (2010) (codified at Social Security Act § 1128B(h), 42 U.S.C. § 1320a-7b(h) (2012))) (noting that the Affordable Care Act amended the criminal intent required to violate Anti-Kickback Statute "by amending Section 1128B of the Social Security Act to state that a defendant does not need specific intent to violate [the statute]").

¹² For the purposes of this Comment, "the government" refers to the Executive Branch, which includes government agencies and the Department of Justice, which represents such agencies in litigation.

¹³ See David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen,"* 30 J. LEGAL STUD. 531, 531-32 (2001) (noting that "health care fraud and abuse control is a booming industry").

¹⁴ See Reinhardt, *supra* note 10.

a statute's application, or simply a difference in interpreting a regulation.¹⁵ Because of these complexities, compliance programs provide important ongoing oversight to reduce negligence and confusion, as well as to identify areas of problematic interpretation.

While the threat of liability is a powerful incentive for health care entities to avoid both intentional and unintentional violations, aggressive enforcement and huge penalties are unlikely to be as effective for unintentional mistakes as for intentional fraud.¹⁶ Unlike intentional fraud, unintentional acts are likely to be conducted by entities already trying to comply with the law.¹⁷ Without ongoing compliance oversight, it is likely that unintentional FCA violations will continue to occur, costing the government and ultimately the taxpayer.¹⁸

However, while it is critical for health care entities to institute robust compliance programs, the current adversarial relationship between the regulated entities and the government regulators impedes this goal. Although health care entities already spend significant resources on compliance programs,¹⁹ health care providers remain fearful of reporting potential violations to compliance officers because health care providers continue to view such officers as adversaries.²⁰ Therefore, efforts to lessen fear and create a more cooperative relationship between the government and health care entities have become a necessary reality.²¹ This Comment will explore the

¹⁵ See Krause, *supra* note 10, at 209–10 (noting that “[w]hile ‘the criminal law has little reason to fear overdeterrence . . . within its appropriate domain,’ the same cannot be said of civil laws such as the FCA” and arguing that “it is precisely when health care providers’ conduct falls within a regulatory gray area . . . that punitive penalties are *least* appropriate” (first ellipsis in original)).

¹⁶ See Hyman, *supra* note 13, at 543 (noting that many physicians convicted of Medicaid fraud had not believed they had been doing anything wrong and further noting the tension between regulation and professional norms in the medical community).

¹⁷ See *id.*

¹⁸ See Reinhardt, *supra* note 10.

¹⁹ See AM. HOSP. ASS’N, PATIENTS OR PAPERWORK? THE REGULATORY BURDEN FACING AMERICA’S HOSPITALS 11 (2006), <http://www.aha.org/content/00-10/FinalPaperworkReport.pdf>.

²⁰ See Michael Miscoc & Alicia Shickle, *Group Practice Liability Under the False Claims Act: Minimizing Liability Through Implementation of an Effective Compliance Program*, in AHLA HEALTH CARE COMPLIANCE RESOURCE GUIDE 3, 6 (2014), https://www.healthlawyers.org/Events/Programs/2014/Documents/Fraud_advertorial_2014.pdf (“Unfortunately, a compliance officer is often seen as an adversary, and where this is the case, a compliance officer often gets little help detecting non-compliance or potentially fraudulent conduct from other employees.”).

²¹ See generally Terry Puchley, Mitchel Harris & Aysha Long, *How Health Care Organizations’ Risk and Compliance Executives Can Become Strategic Board Advisors*, in AHLA HEALTH CARE COMPLIANCE RESOURCE GUIDE, *supra* note 20, at 31, 31–35 (“Being on the front end of strategy-setting allows risk and compliance officers to proactively engage leadership rather than being brought in on the back end to change or remediate the fallout of unadvised decisions.”).

establishment of a privilege for compliance auditing, which is but one tool to promote such openness and cooperation.

This Comment is divided into five parts. Part I describes recent FCA violations within the health care context and explores the recent increase of government enforcement of these violations. Part II then illustrates several ways that compliance auditing is likely to identify current FCA violations and to prevent future FCA violations from occurring; it then discusses potential conflicts with discoverability of audit reporting. Part III describes existing privileges in FCA actions, concluding that existing privileges are unlikely to provide meaningful protection to compliance audits. Part IV explores a current federal privilege for patient-safety data under the Patient Safety and Quality Improvement Act. Part V discusses the differences and similarities between patient-safety efforts and compliance, and concludes that the benefits associated with the patient-safety privilege are likely to benefit compliance in a similar way. Finally, Part VI explores challenges unique to compliance and concludes that, while unlikely to solve all fraud and abuse problems, such a privilege will significantly decrease FCA violations and improve overall compliance for health care entities.

I. THE FALSE CLAIMS ACT WITHIN THE HEALTH CARE CONTEXT

This Part will describe the False Claims Act and recent trends in government enforcement of the Act. This Part will then discuss the differences between intentional and unintentional acts that result in FCA violations and suggest that fear of liability may not be an effective deterrent for unintentional mistakes. This Part concludes with an analysis of two especially complex fraud and abuse laws, the Stark Law and the Anti-Kickback Statute, and an analysis of how the Affordable Care Act has impacted these laws.

The FCA is a federal statute that imposes liability on a person or entity that submits false or fraudulent payment claims to the government.²² In the health care context, a program that bills the Centers for Medicare & Medicaid Services (CMS)²³ for any services not permitted by CMS regulations is in

²² 31 U.S.C. § 3729 (2012).

²³ While CMS is the most common payer, programs that bill other government entities such as CHAMPVA, CHAMPUS/TRICARE, Federal Employee Health Care Program, and other federal health care programs can also create FCA liability. See *Anti-Kickback Statute and the Stark Law*, BERNSTEIN LIEBHARD LLP, <http://www.bernie.com/whistleblowers/Anti-Kickback-Statute/index.html> (last visited Feb. 19, 2016).

violation of the FCA.²⁴ This includes billing for services not actually provided, misrepresenting services or treatments provided, or services or treatments that are defined by CMS as not medically necessary.²⁵

A. Current Government FCA Enforcement Methods Risk Regulatory Disorder

The government enforces FCA violations in two ways: the government may bring a FCA action against an entity or individual, or it may intervene in a private individual's case against an entity or individual.²⁶ A private individual, called a relator or whistleblower, may bring a civil action against an entity or individual for violating the FCA on behalf of the United States under the FCA's qui tam provisions.²⁷ The United States can intervene in such an action and assume primary responsibility, or the relator may proceed with the action if the government declines to intervene.²⁸ Private individuals have a strong financial incentive to file qui tam actions; if the government intervenes, a relator may share in 15%–25% of the award and may receive 25%–30% of the award if the government does not intervene.²⁹ This incentive has been touted as

²⁴ See Joan H. Krause, "Promises to Keep": Health Care Providers and the Civil False Claims Act, 23 CARDOZO L. REV. 1363, 1366 (noting that "[a] health care provider that breaches its promises to the federal government, yet seeks payment as if it had fully performed, engages in a form of health care fraud"); Lonie Kim, Comment, *Am I Liable? The Problem of Defining Falsity Under the False Claims Act*, 39 AM. J.L. & MED. 160, 161 (2013). For an in-depth discussion on the Medicare claims submission and reimbursement processes, see Richard Doan, *The False Claims Act and the Eroding Scientist in Healthcare Fraud Litigation*, 20 ANNALS HEALTH L. 49, 53–55 (2011).

²⁵ 31 U.S.C. § 3729.

²⁶ See 31 U.S.C. §§ 3729–3730.

²⁷ 31 U.S.C. § 3730(b). The term *qui tam* comes from the Latin phrase, "qui tam pro domino rege quam pro si ipso in hac parte sequitur," which means, "who as well for the king as for himself sues in the matter." *Qui Tam Action*, BLACK'S LAW DICTIONARY (10th ed. 2014).

²⁸ 31 U.S.C. § 3730(b)(4)(B), (c)(1). Although this Comment does not specifically discuss the impact of privilege when the government does not intervene in a FCA case, health care entities are forced to combat more potential increases in liability when courts allow relators to have privileged documents that they would not otherwise be allowed to access. In *United States ex. rel. King v. Solvay S.A.*, the court held that relators could add factual allegations to their amended FCA complaint, even though the facts came from documents subpoenaed by the government while the case was under seal. No. H-06-2662, 2010 WL 2851725, at *1 (S.D. Tex. July 20, 2010); see also Marisa Lorenzo, *District of Massachusetts to Determine Whether Relator May Amend Complaint with Documents Subpoenaed by the Government*, LEXOLOGY (Mar. 16, 2011), <http://www.lexology.com/library/detail.aspx?g=f2744ad8-4388-4671-b257-13301f83574c>. Similarly, in *United States ex rel. Banigan v. Organon USA Inc.*, a district court in Massachusetts held that, although the government ultimately decided not to intervene, a relator could use information obtained by the government through a government subpoena to bolster the relators' complaint. No. 07-12153, 2011 WL 794915, at *1–2 (D. Mass. Feb. 28, 2011); see Lorenzo, *supra*.

²⁹ 31 U.S.C. § 3730(d)(1)–(2). Compare William M. Landes & Richard A. Posner, *The Private Enforcement of Law*, 4 J. LEGAL STUD. 1, 15–16 (1975) (describing an economic model of competitive, profit-maximizing private enforcement and arguing that the incentives in private enforcement result in

an important tool for government enforcement, but it may also result in excessive enforcement.³⁰ When considering the incentives and the optimal quantity of litigation from a law and economics analysis, excessive enforcement occurs when the costs of controlling socially undesirable acts—in this case, violating the FCA—is greater than the social benefits associated with reducing the undesirable act from occurring.³¹ Said another way, excessive enforcement occurs “when the violator of a legal rule suffers excessive harm—or more harm than is necessary for optimal deterrence—from the actual implementation of that rule.”³² Excessive enforcement is a concern because it risks regulatory disorder.³³ Disorder can result from “‘excessive unchecked discretion in enforcement authorities’ and the . . . ‘inevitable disparity among similarly situated persons.’”³⁴

Regardless of whether an individual brings a FCA case or if the government intervenes, increased enforcement is unlikely to promote optimal compliance because this type of enforcement is unlikely to effectively alter behavior in all contexts.³⁵ Although behavior is partially influenced by the threat of litigation, a more cooperative relationship between regulators and the regulated industry is likely to make oversight more effective and, therefore,

excessive levels of enforcement), with David Kwok, *Evidence from the False Claims Act: Does Private Enforcement Attract Excessive Litigation?*, 42 PUB. CONT. L.J. 225, 237 (2013) (arguing that private litigation is unlikely to have a significant enforcement impact on alleged FCA violations). According to DOJ published data, between 1987 and 2009, “only 239 out of 3,920 non-intervened cases resulted in a settlement or judgment in favor of the United States, a 6% success rate,” but when DOJ intervened, 1,076 of the 1,134 cases “resulted in a settlement or judgment in favor of the United States, a 95% success rate.” Kwok, *supra*, at 237.

³⁰ See Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281, 300 (2007) (analyzing the Government’s enforcement behavior under a moral hazard theory, the author argues that because “the Government may rely upon the relator . . . to absorb [litigation] costs by prosecuting on the Government’s behalf,” “the Government prosecutes or allows the relator to prosecute excessive numbers of FCA cases that the Government alone would not bring”). For a thoughtful economic analysis of the impact of private enforcement actions, see also Landes & Posner, *supra* note 29.

³¹ See Isaac D. Buck, *Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259, 264 (2015) (noting that we currently have an “enforcement framework that not only over-captures individual providers, but fails to appropriately differentiate providers whose misconduct and individual level of culpability varies”); Steven Shavell, *The Optimal Structure of Law Enforcement*, 36 J.L. & ECON. 225, 261 (1993); Joel P. Trachtman & Philip M. Moremen, *Costs and Benefits of Private Participation in WTO Dispute Settlement: Whose Right Is It Anyway?*, 44 HARV. INT’L L.J. 221 (2003).

³² Richard A. Bierschbach & Alex Stein, *Overenforcement*, 93 GEO. L.J. 1743, 1744 (2005).

³³ Buck, *supra* note 31, at 270.

³⁴ *Id.* (quoting Sara Sun Beale, *The Many Faces of Overcriminalization: From Morals and Mattress Tags to Overfederalization*, 54 AM. U. L. REV. 747, 749 (2005)).

³⁵ Krause, *supra* note 10.

better promote a healthy system of proactive and ongoing compliance.³⁶ This impact can be inferred from the different motivations behind intentionally criminal FCA violations and unintentional violations.³⁷ The following section will first describe three common unintentional FCA violations. The section will then argue that when entities unintentionally submit false claims, a compliance program is a better tool to prevent future errors than are traditional enforcement mechanisms.

B. Unintentional FCA Violations Are Less Likely to Be Influenced by Current Enforcement Strategies

While there have been numerous examples in the news of willful and intentional health care fraud,³⁸ a health care entity can unintentionally violate the FCA in many ways. For example, if a staff member responsible for billing is unaware that his or her medical license has expired, there can be a finding of fraud even if the services were properly rendered.³⁹ If a physician is absent when he or she is required to be in the same room to oversee the performance of a service, which is then billed to CMS, there could be a FCA violation.⁴⁰ If a patient's services are billed on an outpatient basis—but the patient received a service CMS has identified only as an inpatient procedure—this discrepancy may also trigger a FCA violation because CMS has regulated that certain inpatient procedures are not medically necessary for patients receiving outpatient treatments.⁴¹

³⁶ See Buck, *supra* note 31, at 313 (“By employing a random and seemingly disordered enforcement framework, federal prosecutors have risked further stoking tension between medical and legal industries, and instead, may actually be deterring beneficial conduct. . . . [I]t seems time for a recalibration of health care fraud enforcement—one focused on a cooperative enterprise . . .”).

³⁷ See *id.*; see also Krause, *supra* note 24, at 1386 (noting that “[b]ecause of the complexity of federal health care program reimbursement requirements,” health care entities are proactively seeking legal and compliance advice from consultants, accountants, and other advisors).

³⁸ See, e.g., David A. Fahrenthold, *A Medicare Scam that Just Kept Rolling*, WASH. POST (Aug. 16, 2014), <http://www.washingtonpost.com/sf/national/2014/08/16/a-medicare-scam-that-just-kept-rolling/> (describing “the wheelchair scam” where criminals “ginned up bogus bills, saying they’d provided expensive wheelchairs to Medicare patients” who actually did not need them); see also Krause, *supra* note 10, at 124 (noting that “anti-fraud rhetoric now pervades the national health care debate”).

³⁹ Greg Freeman, *6 Ways to Avoid Unintentional Medicare Fraud*, HEALTH LEADERS MEDIA (Jan. 30, 2014), <http://www.healthleadersmedia.com/page-2/HEP-300516/6-Ways-to-Avoid-Unintentional-Medicare-Fraud>.

⁴⁰ See *id.*

⁴¹ See Press Release, U.S. Dep’t of Justice, Georgia Hospital to Pay \$20 Million to Resolve False Claims Act Allegations (Apr. 27, 2015), <http://www.justice.gov/opa/pr/georgia-hospital-pay-20-million-resolve-false-claims-act-allegations>.

These types of mistakes or unintentional violations⁴² more often reflect improper compliance oversight and human error, rather than malicious fraud.⁴³ In these unintentional situations, because health care entities do not intend to participate in fraud, it is likely that improving compliance oversight, rather than simply increasing punishments through regulatory enforcement, will decrease FCA violations.⁴⁴ The following section discusses two important laws related to FCA: The Stark Law and Anti-Kickback Statute (AKS).

C. The Stark Law and Anti-Kickback Statute: Additional Tripwires for Entities

The continued unintentional FCA violations are due in part to the fact that the laws regulating health care entities are extremely complex and have changed and continue to change over time. In addition to general violations of the FCA, there are two regulations the government has particularly focused on in recent enforcement activities: Stark Law violations and AKS violations.⁴⁵

1. The Stark Law: Regulatory Landmines for Health Care Referrals

The Stark Law prohibits physicians from referring Medicare or Medicaid patients for designated health services⁴⁶ to entities that the physician has a

⁴² Another growing area of regulatory enforcement under the FCA is “overtreatment” or “medically unnecessary treatment.” See Buck, *supra* note 31, at 276 (noting that “federal prosecutors have increased their focus on providers who . . . have allegedly administered overtreatment”). This is different than the unintentional violations discussed in this Comment because often “overtreatment results from the divergence between clinical decision-making and government or insurance-created standards” and therefore may be simply a difference in medical opinion rather than mistakes. *Id.* at 277. It would seem that the unintentional mistakes discussed in this Comment are likely to be more easily corrected through compliance programs than overtreatment issues.

⁴³ See Miscoe & Shickle, *supra* note 20, at 5 (noting that “provider groups must take deliberate steps to reduce FCA exposure . . . because physician groups can be directly liable for their own failure to prevent submission of false claims”). *But see* Doan, *supra* note 24, at 57 (discussing how the “sheer complexity of the Medicare and Medicaid systems” makes it especially difficult to “distinguish[] between fraud and mistake,” which suggests that “[p]roviders can easily manipulate complex rules . . . to [purposefully] submit improper claims”).

⁴⁴ Compliance programs are directly aimed at reducing FCA violations. See, e.g., Miscoe & Shickle, *supra* note 20; John P. Kaisersatt, Note, *Criminal Enforcement as a Disincentive to Environmental Compliance: Is a Federal Environmental Audit Privilege the Right Answer?*, 23 AM. J. CRIM. L. 405, 409 (1996) (noting that “both regulators and the regulated community favor the promotion of compliance through self-auditing”).

⁴⁵ 42 U.S.C. § 1395nn (2012); see also Tony R. Maida & Sara Kay Wheeler, *Stark and Anti-Kickback Enforcement Actions: Investigation and Settlement*, AHLA-PAPERS P09250626 (AHLA Seminar Materials 2006) (noting that “[f]inancial arrangements between hospitals and physicians have become the subject of intense legal and regulatory scrutiny”).

⁴⁶ Designated health services include: (1) clinical laboratory services, (2) physical therapy services, (3) occupation therapy services, (4) radiology services (including MRIs, Ultrasounds, and CAT scans),

direct or indirect financial relationship with, unless an exception applies.⁴⁷ Additionally, the Stark Law prohibits entities from billing claims to CMS for these inappropriately referred services; if they are billed, they can then be the basis for a FCA violation.⁴⁸ The Stark Law is a “highly technical statute with numerous technical statutory and regulatory exceptions.”⁴⁹ These complexities are compounded due to the numerous changes to the law in the past twenty years.⁵⁰ In addition to these changing complexities, the Stark Law does not require intent, which means that health care entities are held strictly liable for a violation even if they did not know or intend to violate the law.⁵¹ It is therefore unsurprising that Stark Law violations are a significant part of federal health care enforcement activities.⁵² On one hand, higher enforcement of the Stark Law suggests that many entities are violating the law and therefore greater enforcement is required, but on the other hand, entities may simply be easy targets for Stark Law enforcement solely because the sheer complexity of the law makes it easy for the government to identify a violation and therefore obtain settlements.⁵³

(5) radiation therapy and supplies, (6) durable medical equipment and supplies, (7) parenteral and enteral nutrients, equipment, and supplies, (8) prosthetics, orthotics, and prosthetic devices and supplies, (9) home health services, (10) outpatient prescription drugs, and (11) inpatient and outpatient hospital services. 42 C.F.R. § 411.351 (2014).

⁴⁷ *Physician Self Referral*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/> (last visited Feb. 13, 2014). For a discussion on the various exceptions to the Stark Law, see, for example, Scott Becker, Ji Hye Kim & Jessica L. Smith, *11 Key Concepts from the Stark Law*, MCGUIRE WOODS, https://www.mcguirewoods.com/news-resources/publications/health_care/11%20Key%20%20Concepts.pdf.

⁴⁸ *Physician Self Referral*, *supra* note 47.

⁴⁹ Claire Turcotte, *Keeping Clients Compliant with Stark and Other Health Care Laws*, in HEALTH CARE LAW ENFORCEMENT AND COMPLIANCE at *2, Westlaw 2011 WL 4454656.

⁵⁰ See, e.g., Stark I Final Rule, 60 Fed. Reg. 41,914 (Aug. 14, 1995); Stark II Proposed Rule, 63 Fed. Reg. 1,659 (Jan. 9, 1998); Stark II, Phase I Final Rule, 66 Fed. Reg. 856 (Jan. 4, 2001); Stark II, Phase II, Interim Final Rule, 69 Fed. Reg. 16,054 (Mar. 26, 2004); Stark II, Phase III Final Rule, 72 Fed. Reg. 51,012 (Sept. 5, 2007).

⁵¹ Turcotte, *supra* note 49, at *4–5 (noting “increasing tension between the long-standing idea of the Stark Law as bright-line, strict liability statute and the notion of intent”).

⁵² See, e.g., *id.* at 4 (noting “that the government has begun to recognize the[] advantages of bringing a Stark Law claim to support its FCA case” because the Stark Law lacks any element of intent and “require[s] only proof by a preponderance of the evidence,” as opposed to criminal law, which requires proof beyond a reasonable doubt); see also Ben A. Durie, *Halifax Case Signals Greater Stark Law Enforcement*, HOOPER, LUNDY & BOOKMAN, PC (May 1, 2014), http://www.health-law.com/media/pubperspect/263_Durie%20Web%20Version.pdf (describing several recent FCA Stark Law Cases, including Halifax, Tuomey Healthcare System, and Bradford Regional Medical Center, and several “future high-profile cases on the horizon”).

⁵³ See Buck, *supra* note 31, at 270 (noting that “[i]n the case of overenforcement, ‘if almost the entire community is guilty of some crime, . . . [t]he question of why a particular individual was selected becomes . . .

2. *Anti-Kickback Statute: How the ACA Created Greater AKS Liability*

AKS is a criminal statute that forbids any entity or individual to knowingly or willfully exchange anything of value in an effort to induce the referral of federal health care program business.⁵⁴ For example, feeding the homeless or providing free transportation to a clinic could be considered an AKS violation, if providing meals or improving access to services encourages individuals to seek continued treatment at the hospital.⁵⁵ In this example, a provider could be held personally liable for violating AKS, along with the health care entity that bills the government reimbursement for services that violate AKS.⁵⁶

Although the interpretation of the knowingly or willfully intent requirement has “generated significant controversy and contradictory court rulings,”⁵⁷ the ACA makes clear that actual knowledge of an AKS violation or the specific intent to commit a violation of the AKS is no longer necessary for conviction.⁵⁸ The ACA also clarified that any claims submitted to the government as a result of an AKS violation could trigger liability under the FCA.⁵⁹ For example, if a health care provider had a relationship with a pharmaceutical company that violated AKS, all claims submitted from that

debatable” (alteration in original) (quoting Paul J. Larkin, Jr., *Public Choice Theory and Overcriminalization*, 36 HARV. J.L. PUB. POL’Y 715, 752 (2013)).

⁵⁴ See 42 U.S.C. § 1320a-7b (2012).

⁵⁵ See, e.g., Freeman, *supra* note 39; Michael F. Schaff & Alyson M. Leone, *OIG Provides New Guidance on Free Transportation*, AM. HEALTH LAW. ASS’N (2009), https://www.wilentz.com/files/articlesandpublicationsfilefiles/165/articlepublicationfile/schaff_physorgsjuly09-reprint.pdf (cautioning that while “free transportation may have important and beneficial effects on patient care, it may also be a part of fraudulent or abusive schemes that lead to inappropriate steering of patients, overutilization, and the provision of medically unnecessary services”).

⁵⁶ See Schaff & Leone, *supra* note 55.

⁵⁷ FLEPS, *supra* note 11, § 3:1; see also Patrick J. Miller, *Health Reform Is Not Just Insurance Reform: Significant Changes in Fraud and Abuse Enforcement*, 53 ADVOC., Oct. 2010, at 28, 29 (“The ACA . . . provides that a person may violate the anti-kickback statute even if such person did not know the anti-kickback statute existed and did not specifically intend to violate the anti-kickback statute.”).

⁵⁸ 42 U.S.C. § 1320a-7k; see also JENNIFER A. STAMAN, CONG. RESEARCH SERV., RS22743, HEALTH CARE FRAUD AND ABUSE LAWS AFFECTING MEDICARE AND MEDICAID: AN OVERVIEW 5 (2014) (“[T]he government may still have to prove that the defendant knew that the conduct in question was unlawful, but not that it was a violation of the anti-kickback statute per se. Still, it appears that the amendments made by the ACA may make it easier for the government to prove an anti-kickback statute violation.”).

⁵⁹ See 42 U.S.C. § 6402(f) (“In addition to the penalties provided for in this section . . . a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the [False Claims Act].”); 42 C.F.R. § 1001.952 (2015); see also *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 54–55 (D. Mass. 2011) (citing an extensive list of cases and noting that “courts, without exception, agree that compliance with the Anti-Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti-Kickback Statute”).

provider for a drug or service that was the subject of the AKS violation would automatically create liability for the provider under the FCA, even if a patient received a medical benefit from drug or service received.⁶⁰ Additionally, there are substantially more indictments of individual doctors under the AKS, compared to indictments of individual doctors under the FCA for violations of AKS.⁶¹

However, the individual physician often does not directly bill CMS. Instead, the health care entity employing or contracting with the physician is billing CMS, resulting in the health care entity submitting a false claim and therefore risking liability under the FCA.⁶² This is important to the government because individual providers usually do not have the assets to pay out the damage awards the government normally seeks; the ability to sue the health care entity under FCA for an AKS violation of an individual provider allows the government to sue defendants with deep pockets.⁶³ This may be changing: a recently announced DOJ policy change, commonly referred to as the “Yates Memo,” makes it clear the government intends to “combat corporate misconduct . . . by seeking accountability from the individuals who perpetrated the wrongdoing.”⁶⁴ The increasing government enforcement effort, and its impact on the adversarial relationship between government and health care entities, is further discussed in the following section.

D. The Rise of Government Enforcement Has Exacerbated the Adversarial Nature of the Relationship Between Health Care Entities and the Government

The rise of enforcement of health care fraud in recent years has been an intentional government effort to deter individuals and health care entities from misappropriating public funds.⁶⁵ This enforcement has created a significant

⁶⁰ See, e.g., Nathan Trexler, *Fraud and Abuse: Key Provisions in the PPACA*, DEL. LAW., Spring 2013, at 16, 17 (noting that “a claim submitted in violation of the AKS is necessarily a false claim under the FCA”); see also Scott Oswald & David Scher, *Health Care Law Expands False Claims Act Liability Under the Anti-Kickback Statute*, 26 WESTLAW J. GOV’T CONT., June 11, 2012, at *1 (“Recent court decisions confirm that the measure of damages in [AKS] fraud claims is the full value of the services provided, even though the patients in question often receive the medical benefits claimed . . .”).

⁶¹ See Oswald & Scher, *supra* note 60, at 2.

⁶² *Id.*

⁶³ *Id.* at 3.

⁶⁴ Memorandum from Sally Quillian Yates, Deputy Att’y Gen., to the Assistant Att’y Gen., Antitrust Div., et al. (Sept. 9, 2015), <http://www.justice.gov/dag/file/769036/download>.

⁶⁵ Press Release, U.S. Dep’t of Justice, Justice Department Recovers \$3.8 Billion from False Claims Act Cases in Fiscal Year 2013 (Dec. 20, 2013) [hereinafter Press Release, \$3.8 Billion], <http://www.justice.gov/>

source of revenue for the government by successfully prosecuting FCA allegations and collecting large settlements from health care entities.⁶⁶ However, a purely aggressive “hyper-enforcement”⁶⁷ may be promoting an unnecessarily strong adversarial relationship between the government and health care providers who are making a good-faith effort to follow the laws.⁶⁸

The current adversarial relationship is promoted by the government’s strong messaging efforts directed to the public about the government’s monetary successes in enforcement actions.⁶⁹ These enforcement efforts are touted as large “return on investments”⁷⁰ and a win for “the taxpayer and for the millions of Americans, states agencies and organizations that benefit from government programs and contracts.”⁷¹ Government officials have made it clear they have “taken the government’s fight against health care fraud ‘to a new level.’”⁷² In fact, in 2013, the government recovered \$2.6 billion in health care fraud, up from \$1.7 billion in health care fraud settlements and prosecutions just ten years previously.⁷³

The Government has gone further and has arguably equated health care fraud as a crime similar to drug trafficking, organized crime, and other offenses that merit a strong government response.⁷⁴ In fact, in May 2009, the

opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013 (“The \$3.8 billion in federal [FCA] recoveries in fiscal year 2013, plus another \$443 million in recoveries for state Medicaid programs, restores scarce taxpayer dollars . . . [and] is also a strong deterrent to others who would misuse public funds . . .”).

⁶⁶ *Id.* (“The \$2.6 billion in health care fraud recoveries in fiscal year 2013 marks four straight years the department has recovered more than \$2 billion in cases involving health care fraud.”).

⁶⁷ David L. Douglass & Matthew M. Benov, *Healthcare Fraud Enforcement After Healthcare Reform (Or “More. More. More. How Do You Like It?”)*, 23 HEALTH LAW., Aug. 2011, at 35, 43.

⁶⁸ *See id.*

⁶⁹ *See* Press Release, \$3.8 Billion, *supra* note 65.

⁷⁰ Press Release, U.S. Dep’t of Health & Human Servs., Departments of Justice and Health and Human Services Announce over \$27.8 Billion in Returns from Joint Efforts to Combat Health Care Fraud (Mar. 19, 2015), <http://www.hhs.gov/about/news/2015/03/19/departments-of-justice-and-health-and-human-services-announce-over-27-point-8-billion-in-returns-from-joint-efforts-to-combat-health-care-fraud.html>.

⁷¹ Press Release, \$3.8 Billion, *supra* note 65.

⁷² Douglass & Benov, *supra* note 67, at 36 (quoting Press Release, U.S. Dep’t of Justice, Attorney General Holder and Secretary Sebelius Team Up at Health Care Fraud Prevention Summit in Boston (Dec. 16, 2010), <http://www.justice.gov/opa/pr/attorney-general-holder-and-secretary-sebelius-team-health-care-fraud-prevention-summit>).

⁷³ Press Release, \$3.8 Billion, *supra* note 65; Joan H. Krause, *Healthcare Fraud and Quality of Care: A Patient-Centered Approach*, 37 J. HEALTH L. 161, 163 (2004).

⁷⁴ *See* Michael Volkov, *Healthcare Fraud: Aggressive Enforcement Strategies*, VOLKOV: CORRUPTION, CRIME & COMPLIANCE (Jan. 26, 2015), <http://blog.volkovlaw.com/2015/01/healthcare-fraud-aggressive-enforcement-strategies/> (noting that the “continuing trend of aggressive civil enforcement . . . is being

Department of Justice (DOJ) and the Department of Health and Human Services (HHS) created the Health Care Fraud Prevention and Enforcement Action Team to investigate health care fraud.⁷⁵ This team is referred to as “HEAT” and uses “strike forces” of attorneys in multiple federal agencies working in collaboration to aggressively prosecute fraudulent Medicare billing.⁷⁶ In addition, the Office of Inspector General (OIG)⁷⁷ launched a “Most Wanted Fugitives List” for individuals charged with health care fraud to focus the public’s attention on individuals’ criminal efforts to intentionally defraud the government.⁷⁸ The message is clear: the government is making significant efforts to decrease health care fraud by aggressively seeking legal action against individuals and large entities that violate the FCA.

However, while the government has framed much of its messaging as efforts to crack down on willful and malicious criminal fraud within the health care system, often individuals who willfully defraud the government are judgment proof.⁷⁹ As a result, the government has a significant financial incentive to aggressively pursue large entities with deep pockets for accidental violations, rather than only focus on intentional acts that purposefully defraud the government.

In many ways, this makes sense; from a revenue perspective, it may not matter to the government and to the taxpayer whether an entity purposefully or accidentally allows the government to improperly pay for services. But while intentional crime may be best deterred through severe punishment and punitive damages, unintentional violations are unlikely to be best deterred by the same methods. On one hand, severe punishment will deter unintentional violations because it will make the actors more careful,⁸⁰ but knowledge is another deterrence method to unintentional violations. Incentivizing entities to become

supplemented with new criminal prosecution schemes and tactics typically reserved for organized crime and narcotics trafficking organizations”).

⁷⁵ Douglass & Benov, *supra* note 67, at 42.

⁷⁶ *Id.*

⁷⁷ The OIG is a government agency within the U.S. Department of Health and Human Services. The OIG’s role is to “identify and eliminate fraud, waste, and abuse in HHS programs and to promote efficiency and economy in HHS operations.” Maida & Wheeler, *supra* note 45.

⁷⁸ Douglass & Benov, *supra* note 67, at 42.

⁷⁹ *Id.*; U.S. GEN. ACCOUNTING OFF., GGD-80-7, REPORT OF THE COMPTROLLER GENERAL: DEPARTMENT OF JUSTICE SHOULD COORDINATE CRIMINAL AND CIVIL REMEDIES TO EFFECTIVELY PURSUE FRAUD IN FEDERAL PROGRAMS (1979).

⁸⁰ It is undeniable that large settlements and judgments against entities and individuals who are “made examples of” to other entities promotes internal compliance efforts to prevent government scrutiny, potential legal action, and a negative public image. *See id.*

more knowledgeable about potential violations, rather than only relying on prosecuting violations that have already occurred, is key to creating a healthy, efficient, and affordable health system.⁸¹ One way to increase knowledge of violations and to promote long-term compliance is through compliance auditing,⁸² one way to incentivize auditing is to establish a legal privilege for these audits.⁸³ Part II explores why compliance auditing should be part of an effective compliance program, and how a lack of privilege inhibits entities from realizing the full potential benefits of a compliance program.

II. COMPLIANCE AUDITING: THE MOST EFFECTIVE DETERRENT FOR UNINTENTIONAL FCA VIOLATIONS

Ongoing auditing is critical for a robust compliance program because auditing can identify concerns before problems develop, address possible existing violations in a timely manner, and encourage a culture of cooperation within the entity and between the entity and the government.⁸⁴ The recognized

⁸¹ See, e.g., Cheryl L. Wagonhurst, Janice A. Anderson & Nathaniel M. Lacktman, *The Quality of Care Cerberus: Payments, Public Reporting, and Enforcement*, 20 HEALTH L., Dec. 2007, at 1, 7 (noting that “[a]ddressing quality of care proactively, and integrating it with compliance, will place the [health care entity] . . . on the cutting edge to meet pay-for-performance quality targets . . . [and] can prevent allegations of fraud based on poor quality of care”); *Top 10 Counseling Tips to Minimize Fraud Exposure in an Environment of Heightened Scrutiny*, KATTEN MUCHIN ROSENMAN LLP (June 16, 2010), <http://www.kattenlaw.com/files/upload/Top-10-Counseling-Tips-to-Minimize-Fraud-Exposure.pdf> (describing proactive ways an entity can understand potential violations and policies to prevent violations from occurring).

⁸² The OIG has encouraged entities to develop robust internal compliance programs in order to proactively investigate, correct, and prevent potential FCA violations. See OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858 (Jan. 31, 2005). For example, in 2005, the OIG issued a Supplemental Compliance Program Guidance for Hospitals. *Id.* The guidelines contain compliance recommendations and discuss significant risk areas for hospitals to pay close attention to and recommends a corporate structure that includes a robust compliance program. *Id.* This guidance is meant to promote voluntary compliance and “may serve as a benchmark or comparison against which to measure ongoing efforts and as a roadmap for updating or refining [hospital] compliance plans.” *Id.* OIG also uses Corporate Integrity Agreements (CIAs) to encourage hospitals to settle allegations of fraud and abuse. See Maida & Wheeler, *supra* note 45. Maida and Wheeler state that “CIAs are routinely administered in connections with OIG’s settlement of a FCA investigation” and are used to “rehabilitate providers” by requiring providers to “affirmatively agree to pursue specific remedial steps going forward to prevent the recurrence of alleged improper conduct.” *Id.*

⁸³ See Kathryn Ehler-Lejcher, *The Expansion of Corporate Compliance: Guidance for Health Care Entities*, 25 WM. MITCHELL L. REV. 1339, 1378–79 (1999) (“The primary goal of a corporate compliance program is to prevent violations of the law.”).

⁸⁴ See OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. at 4,858, 4,876; see also HEALTHCARE MGMT. & AUTOMATION SYS., INC., SAMPLE HEALTHCARE COMPLIANCE PROGRAM 1 (2010); Michael A. Dowell, *Hospital-Physician Transaction Compliance Strategies to Address Recent Fraud and Abuse Enforcement Actions*, 16 J. HEALTH CARE COMPLIANCE, Mar.–Apr. 2014, at 5, 20 (“The

benefits of an ongoing auditing program suggest it is an important mechanism for improving overall compliance.⁸⁵ However, these benefits may be stifled if providers are fearful of openly discussing compliance issues; overall compliance will be improved if a compliance audit privilege is recognized.

A. Auditing Improves Regulatory Compliance

The prevalence of inadvertent FCA violations strongly suggests that compliance oversight cannot simply be based on goodwill and best efforts of individual employees because entities and providers are often unaware violations are occurring.⁸⁶ Instead, a systematic approach that specifically addresses problematic areas for potential violations is necessary for compliance programs; identification of problematic areas can be done through ongoing auditing.⁸⁷

There is no single best hospital compliance program, as the OIG has noted,⁸⁸ but a strong program has certain important characteristics. This Part will discuss three ways a compliance program can improve regulatory compliance. First, strong compliance programs establish controls for physician contracting. Second, standard checklists provide standardized processes to protect against human error. Third, databases ensure necessary analyses are conducted and documented.

First, on an entity-wide level, an audit will analyze the current system for the physician contracting process and identify who is involved in negotiating contracts.⁸⁹ By identifying individuals who are directly and indirectly involved in contract negotiations, an entity can better prevent inappropriate relationships from occurring.

Second, after an audit of current employment contracts and other hospital-physician transactions, an entity may identify areas of increased risk associated with specific types of contracting, potential issues arising from medical office leases, or even potentially improper medical education and

development and implementation of an effective compliance program that addresses hospital-physician transaction compliance risks is the best way to address the recent fraud and abuse enforcement actions.”).

⁸⁵ See Dowell, *supra* note 84, at 25.

⁸⁶ See Miscoe & Shickle, *supra* note 20, at 4 (“[H]ospitals and health care provider groups face substantial FCA liability as a result of the conduct of those employed . . .”).

⁸⁷ *Id.* at 5.

⁸⁸ OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. at 4,859 (noting that “[g]iven the diversity of the hospital industry, there is no single ‘best’ hospital compliance program”).

⁸⁹ See Dowell, *supra* note 84, at 21 (discussing ways to manage hospital-physician transactions).

teaching arrangements.⁹⁰ Strategies to improve compliance may include changing standard employment forms to include red flags if specific information is likely to create a conflict, identifying higher risk contracting that must be reviewed by legal counsel, or changing the way the health care entity performs pre-payment and post-payment review of physician contracts.⁹¹ Checklists specifically tailored to the individual health care entity can provide a standardized process to analyze financial relationships and to identify a risk area before it becomes a violation.⁹²

Third, databases can provide a reliable ongoing tracking system for all agreements; auditing may identify the need to include specific input variables, such as requiring a description of the need for services, or confirming legal review and approval of certain arrangements.⁹³ Tracking software can send notifications if, for example, payments are made to a physician without a current contract or if an agreement is about to expire and has not been renewed.⁹⁴

Recent AKS enforcement actions have been brought against health care entities, alleging inappropriate compensations of health care providers and other contracting arrangements.⁹⁵ For this reason, various strategies should be in place to identify and prevent these types of violations from occurring. For example, health care entities should ensure that hourly wages for medical personnel are based on Fair Market Value (FMV), and that loans and travel expense reimbursements are properly performed and not in violation of AKS or Stark Law.⁹⁶ Auditing can reveal a possible need to ensure FMV analyses and commercial reasonableness analyses are performed and properly documented.⁹⁷

For example, submitting a reimbursement claim for a service not actually performed, or medication ordered but not picked up by the patient, constitutes

⁹⁰ *See id.*

⁹¹ *See id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.* at 23.

⁹⁵ *See, e.g., Cooper Health Settlement Agreement*, U.S. DEP'T JUST. (Jan. 24, 2013), <http://www.justice.gov/usao/nj/Press/files/pdf/2013/Cooper%20Health%20Settlement%20Agreement.pdf> (noting problematic arrangements where hospitals allegedly provided services to physicians for free or less than fair market value and allegedly compensated physicians at inflated rates).

⁹⁶ *See Dowell, supra* note 84, at 18 (discussing Memorial Health Care System settlement, including alleged medical office leases below FMV intended to induce physicians to refer patients to Memorial).

⁹⁷ *Id.* at 22.

a false claim.⁹⁸ However, auditing can reveal if staff are not properly utilizing the current system, which could suggest a need to alter the system or require additional staff training. For example, if staff consistently “override” a prompt that asks whether there was confirmation that medication was received, instead of actually confirming the order, staff will need to be retrained on how to confirm medication receipt and the importance of adhering to these types of prompts.

B. Discoverability of Ongoing Auditing Discourages Fully Achieving the Advantages of Compliance Programs

This section will discuss how the lack of protection for compliance audit reports is a barrier for fully implementing ongoing auditing. The OIG strongly suggests health care entities perform ongoing monitoring, which includes daily, weekly, monthly and annual reviews for different types of compliance issues.⁹⁹ Additionally, the OIG has emphasized that a successful compliance program can demonstrate to the government that a health care entity takes compliance seriously and is making a good faith effort to comply with the statutes and regulations governing health care.¹⁰⁰

Because of this, there may be situations where a health care entity would want to disclose to the government its ongoing reviews and reports to show good faith effort and a robust compliance program.¹⁰¹ While there are significant benefits to ongoing auditing, however, it comes at a cost to the health care entity; not only in the time and resources required to conduct audits, but also the legal risks associated with discovering and analyzing potential violations identified through the auditing process.¹⁰² While being proactive can advantage a health care entity because it prevents future violations, entities remain concerned with the discoverability of documents

⁹⁸ See *supra* note 39 and accompanying text.

⁹⁹ OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858 (Jan. 31, 2005); *Affordable Care Act Provider Compliance Programs: Getting Started Webinar*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 26, 2014), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/MLN-Compliance-Webinar.pdf>, see also Dowell, *supra* note 84, at 22.

¹⁰⁰ OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. at 4,859.

¹⁰¹ For a more detailed discussion on when a health care entity may want to disclose information, and the potential issue of subject matter waivers, see *infra* Part VI.

¹⁰² See Kaisersatt, *supra* note 44, at 419.

created by internal auditing and the potential for these documents to be used in criminal and civil actions against them.¹⁰³

Although the discoverability of individual violations, such as identifying an individual overpayment or an individual problem with a physician's contract, is of concern, far more concerning is the risk of not protecting internal controls and potential risk assessments, or corrective action plans. The current privileges in place, discussed in the following Part, are unlikely to protect these analyses from discovery, potentially discouraging health care entities from performing these types of in depth reviews.¹⁰⁴ Therefore, a compliance privilege is necessary.

III. THE CURRENT PRIVILEGES IN FCA ACTIONS PROVIDE NO PROTECTION FOR COMPLIANCE AUDITS

If a health care entity is sued by the government or by a private individual through a qui tam action under the FCA, generally all applicable documents and reports are available for discovery.¹⁰⁵ Although the Federal Rules of Civil Procedure "strongly favor full discovery whenever possible,"¹⁰⁶ there are certain exceptions to the rule, including work product privilege,¹⁰⁷ attorney-client privilege,¹⁰⁸ and peer review privilege.¹⁰⁹ Unfortunately, these exceptions to the general rule are unlikely to provide any meaningful protection to compliance auditing.¹¹⁰ This Part will discuss work product

¹⁰³ *Id.* at 406 (discussing environmental regulation enforcement and the role of internal auditing).

¹⁰⁴ *Id.*

¹⁰⁵ See Keith D. Barber, David B. Honig & Neal A. Cooper, *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*, 1 IND. HEALTH L. REV. 135, 161 (2004) ("One of the most disturbing trends in false claims law for health care providers has been the filing of general allegations by qui tam relators who hope to create a case through the discovery process. . . . which can include every claim submitted to Medicare or Medicaid over a six-year period . . ."); see also FED. R. CIV. P. 9(b).

¹⁰⁶ United States *ex rel.* Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002-Orl-31TBS, 2012 WL 5415108, at *2 (M.D. Fla. Nov. 6, 2012) (quoting *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985)).

¹⁰⁷ See FED. R. CIV. P. 26(b)(3).

¹⁰⁸ See FED. R. CIV. P. 26(b)(5); see also *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 789, 795 (E.D. La. 2007) (describing the five elements of the attorney-client privilege: (1) an attorney, (2) a client, (3) a communication, (4) confidentiality anticipated and preserved, and (5) legal advice being the purpose of the communication).

¹⁰⁹ See *infra* Part V (discussing the Patient Safety Quality Improvement Act).

¹¹⁰ Additionally, because courts generally disfavor granting privilege, courts will narrowly construe privilege and place the burden of proof on the party asserting its protection from discovery. See *Baklid-Kunz*, 2012 WL 5415108, at *3; *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2008 WL 1995058, at *3 (M.D. Fla. May 7, 2008).

privilege, attorney–client privilege, and the peer review privilege. The following Part will compare current peer review with compliance, concluding that a new compliance privilege should be recognized.

A. Work Product Privilege Cannot Protect Ongoing Auditing Efforts

Work product privilege does not protect documents created in the ordinary course of business, and is therefore unlikely to provide meaningful protection to ongoing compliance auditing.¹¹¹ Work product privilege provides protection to any material created by a lawyer “in the course of his [or her] legal duties, provided that the work was done ‘with an eye toward litigation.’”¹¹² While it is plausible to assert that all compliance activities are conducted for the purpose of possible litigation, courts have not interpreted “in preparation for litigation” so broadly.¹¹³ Instead, courts have limited the application of work product privilege to only imminent litigation.¹¹⁴ Because compliance oversight and auditing should be conducted on an ongoing basis in the “ordinary course of business,” the work product privilege is unlikely to provide protection.¹¹⁵

B. Compliance Officers Cannot Invoke Attorney–Client Privilege

Courts are unlikely to grant attorney–client privilege to internal audits conducted by compliance officers.¹¹⁶ Attorney–client privilege protects private communication concerning legal representation between an attorney and his or her client.¹¹⁷ This privilege has been interpreted not to apply to any other advice, such as business advice or communication strategies.¹¹⁸ Given courts’

¹¹¹ See John Calvin Conway, Note, *Self-Evaluative Privilege and Corporate Compliance Audits*, 68 S. CAL. L. REV. 621, 633 (1995).

¹¹² *In re Sealed Case*, 676 F.2d 793, 809 (D.C. Cir. 1982) (quoting *Hickman v. Taylor*, 321 U.S. 495, 511 (1947)); see also *Hager v. Bluefield Reg’l Med. Ctr., Inc.*, 170 F.R.D. 70, 77 (D.C. Cir. 1997) (holding that work product privilege applied to a legal opinion letter written by a law firm to a doctor regarding whether the doctor’s employer’s billing practices violated AKS because it was written in anticipation of future litigation).

¹¹³ Conway, *supra* note 111, at 633.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 633–34.

¹¹⁶ *Cf. United States v. Austin Radiological Ass’n*, No. A-10-CV-914-AWA, 2013 WL 1136668, at *5 (W.D. Tex. Mar. 18, 2013) (noting “it is clear that documents retained by its compliance officer are subject to discovery”); *United States ex rel. Frazier v. IASIS Health Care Corp.*, No. 2:05-cv-766-R CJ, 2012 WL 130332, at *11 (D. Ariz. Jan. 10, 2012) (holding that reports were protected under attorney–client privilege because the reports were not created for the purpose of compliance review).

¹¹⁷ Conway, *supra* note 111.

¹¹⁸ See *Super Tire Eng’g Co. v. Bandag Inc.*, 562 F. Supp. 439, 441 (E.D. Pa. 1983) (noting that the communication’s primary purpose must be to gain or provide legal advice in order to assert privilege, and cannot be sought primarily for business advice).

narrow interpretation of attorney–client privilege, this privilege is unlikely to be a useful defense for health care providers attempting to protect compliance audits.¹¹⁹ In fact, courts routinely have not granted attorney–client privilege in these situations.¹²⁰

If advice is equally sought for both business and legal reasons, courts are unlikely to uphold the privilege because the advice was not *primarily* legal advice.¹²¹ However, refusing to recognize advice that is both legal and business results in an impractical distinction for health care entities because bifurcating legal advice from business advice has proven especially difficult in the corporate context of highly regulated fields like health care.¹²² Assigning a binary label to advice is difficult because in-house counsel and compliance teams serve cross-functional roles in both business strategy and regulatory compliance.¹²³ Health care entities, “operating in today’s labyrinthine legal and regulatory environments,” seek advice from legal counsel on a wide variety of issues, which are likely to include both legal and business related implications.¹²⁴

For example, suppose a health care entity is interested in instituting a new cardiovascular outreach program, which is intended to provide a service to the community and to increase profits for the health care entity.¹²⁵ However, the

¹¹⁹ See *United States v. Int’l Bus. Machs. Corp.*, 66 F.R.D. 206, 213 (S.D.N.Y. 1974) (holding that “[i]f the document was prepared for purposes of simultaneous review by legal and non-legal personnel, it cannot be said that the primary purpose of the document is to secure legal advice”). *But see* FLEPS, *supra* note 11, § 4 (noting there are ways to strategically maximize attorney–client privilege in a compliance audit).

¹²⁰ See, e.g., *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002-Orl-31TBS, 2012 WL 5415108, at *2 (M.D. Fla. Nov. 6, 2012) (holding that internal compliance audits performed by the compliance department cannot be privileged under attorney–client exception because the audits were not communications between legal counsel and for the purpose of seeking legal advice); *Frazier*, 2012 WL 130332, at *11 (holding that reports created for the purpose of compliance review are not protected under attorney–client privilege).

¹²¹ See *supra* note 119 and accompanying text.

¹²² See, e.g., PRICEWATERHOUSECOOPERS, 2014 STATE OF COMPLIANCE SURVEY: WHAT IT MEANS TO BE A “CHIEF” COMPLIANCE OFFICER: TODAY’S CHALLENGES, TOMORROW’S OPPORTUNITIES 2–3 [hereinafter STATE OF COMPLIANCE SURVEY], <https://www.pwc.com/mx/es/riesgos/archivo/2015-03-challenges.pdf>.

¹²³ *Id.* at 2–3.

¹²⁴ *In re Sulfuric Acid Antitrust Litig.*, 235 F.R.D. 407, 424 (N.D. Ill. 2006); see also Puchley et al., *supra* note 21, at 31 (“To gain a deeper understanding of the challenges facing their organizations, board members are looking to audit compliance committees, general counsel, chief compliance officers (CCOs), and internal audit executives to provide analysis and insight into the operational performance and regulatory risks that affect their businesses.”).

¹²⁵ See, e.g., *Cardiovascular Outreach Program*, MAYO CLINIC, <http://www.mayoclinic.org/departments-centers/cardiovascular-diseases/overview/specialty-groups/cardiovascular-outreach-program> (last visited Feb. 29, 2016).

program may also trigger AKS, for example, because of claims that the program spurs overutilization or medically unnecessary services. When the health care entity seeks advice from counsel, an attorney is likely to give business advice on how to structure the program to minimize costs and maximize profits, as well as how to avoid fraud and abuse violations. Conversely, many compliance officers are not attorneys and, therefore, cannot give protected legal advice, even though these persons are highly knowledgeable about the law and regulatory compliance.¹²⁶

While compliance has significant legal implications and requires legal analysis, compliance serves a role in a corporation distinct from that of their general counsel counterparts. In fact, the OIG has strongly encouraged separation of compliance programs from the health care entity's general counsel because an independent compliance program helps "ensure independent and objective legal review and financial analyses of the institution's compliance efforts and activities."¹²⁷ Compliance officers "should be charged with and empowered to *reveal issues*—and may even advocate disclosing to, and cooperating with, the government in certain instances," while the general counsel's role should be "to rigorously defend the company."¹²⁸ Because of the different and sometimes conflicting goals of counsel and compliance, there is a significant conflict of interest concern.¹²⁹

¹²⁶ Even compliance officers who are licensed attorneys may not be able to give protected legal advice through their capacity as a compliance officer; licensed attorneys may only give protected legal advice through their capacity as an attorney. See *United States ex rel. Frazier v. IASIS Health Care Corp.*, No. 2:05-cv-766-RCJ, 2012 WL 130332, at *2–3 (D. Ariz. Jan. 10, 2012) (finding that a Chief Compliance Officer, who was also a licensed attorney, was not acting in his legal capacity and therefore communication was not protected under attorney–client privilege, even though he worked closely with the Legal Department and held himself out "to internal and external audiences as being among the legal counsel employed by the company").

¹²⁷ U.S. DEP'T HEALTH & HUMAN SERVS. & AM. HEALTH LAWYERS ASS'N, AN INTEGRATED APPROACH TO CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE ORGANIZATION BOARDS OF DIRECTORS 1 (2004) [hereinafter OIG INTEGRATED APPROACH TO CORPORATE COMPLIANCE] (quoting Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,993 n.35 (1998)); see also STATE OF COMPLIANCE SURVEY, *supra* note 122, at 11 ("Federal guidelines aside, there's an inherent difference between the roles of [Chief Compliance Officer] and general counsel.").

¹²⁸ STATE OF COMPLIANCE SURVEY, *supra* note 122, at 11 (emphasis added); see also OIG INTEGRATED APPROACH TO CORPORATE COMPLIANCE, *supra* note 127, at 2–3 (noting that General Counsel has "the primary responsibility for assuring an effective legal compliance system" but that a Chief Compliance Officer has the "primary functional responsibility for the day-to-day operations of the compliance and ethics program" (quoting JAMES H. CHEEK ET AL., REPORT OF THE AMERICAN BAR ASSOCIATION, TASK FORCE ON CORPORATE RESPONSIBILITY (2003))).

¹²⁹ Or, as Iowa Representative Charles Grassley more colorfully noted, when an individual is both General Counsel and Chief Compliance Officer, "[i]t doesn't take a pig farmer from Iowa to smell the stench of conflict in that arrangement." Chuck Grassley, *Grassley Investigates Tenet Healthcare's Use of Federal Tax Dollars* (Sept. 7, 2003), [http://www.grassley.senate.gov/news/news-releases/grassley-investigates-tenet-](http://www.grassley.senate.gov/news/news-releases/grassley-investigates-tenet)

This concern is likely to lead to conflicting goals and therefore supports the need for a compliance privilege in order to protect the unique differences between compliance and general counsel.¹³⁰

The current application of attorney–client privilege discourages health care organizations from keeping compliance and legal roles fully distinct because the only privilege currently available is through an attorney acting in a legal capacity.¹³¹ The lack of a compliance privilege creates an unjustified inconsistency when advice from a lawyer creates a privilege, but the same advice from a just-as-qualified compliance officer is not protected under the currently recognized privileges.¹³² Health care entities should be encouraged to implement an independent and stand-alone role for compliance that is completely separate from general counsel. Therefore, a privilege for internal compliance auditing may incentivize proper reliance on compliance, rather than general counsel, for compliance related issues.

C. Peer Review Privilege Has Advanced Patient Safety and Quality

In the health care context, peer review is the process that engages health care providers and other medical personnel to analyze critically how health care activities are performed in order to decrease medical error and improve overall quality.¹³³ Sometimes called Quality Improvement Privilege, these peer review processes may include root cause analyses,¹³⁴ aggregation and analysis

healthcares-use-federal-tax-dollars (reproducing Letter from Charles Grassley, Chairman of the Comm. on Finance, to Trevor Fetter, Acting Chief Exec. Officer and President of Tenet Healthcare Corp. (Sept. 7, 2003)).

¹³⁰ STATE OF COMPLIANCE SURVEY, *supra* note 122, at 11.

¹³¹ See Jonathan Sack, *When Is an Internal Investigation Not Privileged?*, FORBES (Apr. 16, 2014, 4:26 PM), <http://www.forbes.com/sites/insider/2014/04/16/when-is-an-internal-investigation-not-privileged/> (noting that a “recent decision by U.S. District Judge James S. Gwin in the District of Columbia shows that a company’s answer to [whether compliance staff or in-house legal counsel should look into potential misconduct] will affect whether the investigation is subject to the attorney–client privilege” and further noting that “a company’s internal compliance function is distinct from its legal one, and investigations conducted pursuant to a compliance function by compliance personnel will not be viewed as privileged”).

¹³² See, e.g., *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 789, 797 (E.D. La. 2007) (noting the difficulties in applying attorney–client privilege to health care because of the “uniquely regulated nature” of the industry and “the role that in-house counsel has been given in the [company’s] decision-making process”).

¹³³ See, e.g., Kenneth R. Kohlberg, *The Medical Peer Review Privilege: A Linchpin for Patient Safety Measures*, 86 MASS. L. REV. 157, 157–58 (2002) (describing medical peer review privilege); Kathryn Leaman, *Let’s Give Them Something to Talk About: How the PSQIA May Provide Federal Privilege and Confidentiality Protections to the Medical Peer Review Process*, 11 MICH. ST. U. J. MED. & L. 177, 179–80 (2007) (describing medical peer review privilege and predicting how the PSQIA will likely impact the medical peer review process).

¹³⁴ See *infra* note 185 and accompanying text.

of patient safety data,¹³⁵ and conversations with health care providers.¹³⁶ To promote candid discussion, a peer review privilege encourages frank dialogue on issues that health care providers may otherwise be reluctant to openly discuss for fear of potential liability.¹³⁷ The following Part describes a specific federal peer review privilege, the Patient Safety and Quality Improvement Act of 2005 and explores how courts have interpreted this privilege.

IV. FEDERAL PEER REVIEW PRIVILEGE IN ACTION: THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT

Congress enacted a new peer review federal privilege within the health care setting with the Patient Safety and Quality Improvement Act of 2005 (PSQIA).¹³⁸ The PSQIA encourages individual health care entities to create internal reporting systems for patient safety events¹³⁹ to identify and to address proactively systematic risks to health and safety by protecting specific analyses from discovery in future litigation.¹⁴⁰ This “systemic review of error” recognizes the relationship between effective ongoing oversight and improvement of health care quality.¹⁴¹

This Part will first discuss the events leading up to the PSQIA, most notably the recognition that entities were reluctant to collect safety data for fear of potential liability. Second, the Part will discuss how the privilege has significantly expanded patient safety data collection, which in turn has improved patient health. Finally, this Part will discuss the limitations of the PSQIA privilege.

A. A Culture of Fear: Before the PSQIA Protected Patient Safety Data

Before the PSQIA was enacted, the medical community and legislators recognized that health care providers were very reluctant to report errors beyond what they were legally required to report for fear disclosures would be

¹³⁵ See *infra* Part V.A.1.

¹³⁶ See, e.g., Leaman, *supra* note 133, at 197–98.

¹³⁷ See, e.g., Kohlberg, *supra* note 133, at 157.

¹³⁸ 42 U.S.C. § 299b-22 (2012).

¹³⁹ “Patient safety events” is a broad term applicable to any event or action that results in a worsened patient outcome and often results from a preventable medical mistake or error. See NAT’L QUALITY FORUM, PATIENT SAFETY TERMS AND DEFINITIONS (2009), https://www.qualityforum.org/Topics/Safety_Definitions.aspx.

¹⁴⁰ Frederick Levy et al., *The Patient Safety and Quality Improvement Act of 2005: Preventing Error and Promoting Patient Safety*, 31 J. LEGAL MED. 397, 397 (2010).

¹⁴¹ *Id.* at 407.

used against them in legal and regulatory proceedings.¹⁴² To address this problem and incentivize voluntary reporting, the PSQIA established a federal privilege for data, reports, and analysis conducted through a patient safety evaluation system (PSES).¹⁴³ A PSES is not only the event reporting mechanism, but the entire system of patient safety and quality improvement data collection, event reporting, committee activities, peer review, and board reporting that is conducted to send information to a patient safety organization (PSO).¹⁴⁴ The data collected in a PSES is sent to an independent PSO, which aggregates data from multiple health care entities and provides meaningful analysis and feedback on common safety issues and recommendations to prevent future occurrences.¹⁴⁵

Although courts are usually hesitant to expand privileges, the judiciary has generally recognized the strong public interest in maintaining this peer review privilege.¹⁴⁶ In fact, most state courts have determined that private and public interests are served by the medical peer review privilege because the hospital's review process depends on upholding confidentiality.¹⁴⁷

Another notable aspect of the federal PSQIA privilege is that it creates a “floor,” allowing states to grant more privilege than PSQIA provides, but states

¹⁴² See *id.* at 399.

¹⁴³ See *id.*; see also 42 C.F.R. § 3.20 (2010).

¹⁴⁴ See ECRI INST. PSO, PSES PATHWAY: A TOOLKIT TO GUIDE THE DEFINITION, IMPLEMENTATION, AND MANAGEMENT OF A PSES 23 (2013) (“While event and incident reports and associated analysis may be the most common elements of a PSES, organizations are encouraged to think more expansively about the breadth of safety and quality information and analysis within the organization. The [omitted] diagram . . . shows that a PSES potentially traverses the organizational hierarchy, drawing on content from the board of directors to the front line.”).

¹⁴⁵ See Kelly G. Dunberg, Note, *Just What the Doctor Ordered? How the Patient Safety and Quality Improvement Act May Cure Florida's Patients' Right to Know About Adverse Medical Incidents (Amendment 7)*, 64 FLA. L. REV. 513, 514 (2012) (noting that by analyzing and aggregating data submitted to PSOs, “PSOs foster an environment in which providers can learn from their mistakes and the mistakes of others”).

¹⁴⁶ See, e.g., *Veith v. Portage Cty.*, No. 5:11CV2542, 2012 WL 4850197, at *2 (N.D. Ohio Oct. 11, 2012) (noting that “without a peer review privilege, physicians will be discouraged from participating in the full and frank expression of opinion that is essential if peer review is to fulfill its vital role in advancing the quality of medical care” (quoting *Sevilla v. United States*, 852 F. Supp. 2d 1057, 1060 (N.D. Ill. 2012)); *Francis v. United States*, No. 09 Civ. 4004(GBD)(KNF), 2011 WL 2224905, at *4–7 (S.D.N.Y. May 31, 2011). The court held that PSQIA did not protect the review documents because the documents were not provided to a PSO, but the court also held that documents provided to the Department of Health met many of the same qualifying criteria for PSOs and performed similar functions. *Id.* at *6. The court found Congress's intent was to promote broad protection and therefore that recognizing a medical peer review privilege in the Federal Tort Claim Act would advance Congress's goal of promoting peer review to improve quality of care. *Id.* at *6–7.

¹⁴⁷ See *Francis*, 2011 WL 2224509, at *5; Ghazal Sharifi, *Is the Door Open or Closed? Evaluating the Future of the Federal Medical Peer-Review Privilege*, 42 J. MARSHALL L. REV. 561, 563–65 (2009).

cannot take away any protections afforded by PSQIA.¹⁴⁸ When states provide for more privileges than the PSQIA, federal courts will generally follow state law.¹⁴⁹

B. A National Success Story: How the PSQIA Privilege Improves Safety

Since the PSQIA privilege was enacted, there are numerous examples where hospitals have used data, previously not collected because of the lack of legal protections, to improve quality and safety.¹⁵⁰ For example, after collecting data on medical chart errors, hospitals participating in one PSO suggested all hospital professionals stop using certain abbreviations on medical records because the abbreviations were too similar and were easily misread.¹⁵¹

The privilege is not only useful in analyzing previous errors that occurred, including those resulting in harm to patients. It also protects analyses of “near misses,” thus preventing errors that almost happened from ever occurring in the future.¹⁵² There are many examples of how the privilege prevents errors that almost happened from actually happening in the future. The Joint

¹⁴⁸ Many states extend the privilege to internal reporting and do not require data be sent to a PSO. *See, e.g.*, 735 ILL. COMP. STAT. ANN. 5/8-2102 (West 2003) (“All information, interviews, reports, statements, memoranda . . . of a health care practitioner’s professional competence, or other data of . . . committees . . . used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care . . . shall be privileged . . .”); TENN. CODE ANN. § 68-11-272 (West 2015) (information collected by an internal Quality Improvement Committee is privileged). *But see, e.g.*, Memorandum and Order, *Morgan v. Cmty. Med. Ctr. Healthcare Sys.*, No. 2008 CV 4859, at *6 (Ct. Com. Pl. 2010) (narrowly interpreting PSQIA privilege to mean that “if any document is prepared or created for any other or additional purpose,” the document loses all privileges and protection from discovery).

¹⁴⁹ *See* FED. R. EVID. 501 (providing that “in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision”); *see also* *Warren v. Sheriff of Cook Cty.*, No. 09-CV-3512, 2013 WL 5835771, at *2 (N.D. Ill. Oct. 30, 2013) (upholding state privilege, acknowledging that a “strong policy of comity between state and federal sovereignties impels federal courts to recognize state privileges where this can be accomplished at no substantial cost to federal substantive and procedural policy”).

¹⁵⁰ MHA KEYSTONE CTR., PATIENT SAFETY AND QUALITY ANNUAL REPORT 2013, at 10 (2013) (discussing specific initiatives to improve pressure ulcers and adverse drug events, and an analysis on falls that identified “key contributing factors to better prevent future occurrences”).

¹⁵¹ There is significant anecdotal evidence suggesting patient safety improvements. *See, e.g., id.*; Brief for the Joint Commission as *Amicus Curiae* in Support of Appellant Norton Hospital, Inc.’s Interpretation of the Patient Safety Act at 6, *Norton Hosps., Inc. v. Cunningham*, No. 2012-SC-000604 (Ky. Oct. 26, 2012) [hereinafter *JC Amicus Brief*]. Additionally, in January 2010, the U.S. Government Accountability Office (GAO) issued a report to Congress explaining it was too early in the implementation process to fully evaluate the PSQIA’s effectiveness. U.S. GOV’T ACCOUNTABILITY OFF., GAO-10-281, PATIENT SAFETY ACT: HHS IS IN THE PROCESS OF IMPLEMENTING THE ACT, SO ITS EFFECTIVENESS CANNOT YET BE EVALUATED (2010). This is because, although the PSQIA was signed into law in 2005, the implementation of the rule only became effective in 2009. *See* Levy et al., *supra* note 140, at 407.

¹⁵² *JC Amicus Brief, supra* note 151, at 6.

Commission, a not-for-profit corporation that accredits health care organizations, describes how this type of prevention occurs:

For example, as has happened, a physician may accidentally misplace a decimal point when entering a medication order in a patient's chart. A nurse might catch the inadvertent error, the physician would correct the error, and no harm would come to the patient. But the same error could easily occur again, and this time, another nurse might administer the medication to the patient, resulting in serious harm. In the new world of patient safety organizations, the hospital would be able to submit the 'near miss' to the patient safety organization without fear of creating evidence that could be used against the hospital or the individuals involved. The patient safety organization would analyze the near miss event, along with other similar events submitted by other hospitals, and develop and disseminate recommendations, protocols, or feedback regarding the best way to avoid misplaced decimals points in this type of medication order.¹⁵³

By creating an environment where potential errors are reported and openly discussed, without fear of retribution or legal consequence, new data is being collected and shared to improve the health care system.

C. Privilege Does Not Create Blanket Immunity: Finding the Right Balance Between Privilege and Discovery

While the PSQIA promotes a broad privilege, the Act does not protect the underlying data, medical records, or data already required to be reported to agencies by law.¹⁵⁴ For example, an error analysis report would be protected from discovery, but the individual medical, billing, or discharge records used to create the report would not be privileged under the PSQIA.¹⁵⁵

Protecting analyses while ensuring the availability of underlying documents in discovery promotes a proper balance between privilege and discovery of evidence. In a senate floor speech prior to passing the PSQIA, the late-Senator Edward Kennedy discussed this careful balance:

¹⁵³ *Id.* at 10.

¹⁵⁴ See Levy et al., *supra* note 140, at 407–11.

¹⁵⁵ See *id.* at 411; see also Francis v. United States, No. 09-Civ.-4004(GBD)(KNF), at *7 (S.D.N.Y. May 31, 2011) (holding that a doctor's report and the hospital's plan of correction were protected from disclosure, but chronologies were not protected because they included no analysis and therefore not subject to the privilege).

The Institute [of Medicine] recommended that health care professionals should be encouraged to report medical errors, without fearing that their reports will be used against them. Our legislation implements this sensible recommendation by establishing patient safety organizations to analyze medical errors and recommend ways to avoid them in the future. . . .

Drawing the boundaries of this privilege requires a careful balance[.] . . . The bill is intended to make medical professionals feel secure in reporting errors without fear of punishment, and it is right to do so. But the bill tries to do so carefully, so that is it does not accidentally shield persons who have negligently or intentionally caused harm to patients.¹⁵⁶

The PSQIA does not create blanket immunity for health care providers.¹⁵⁷ Rather, as Senator Kennedy stressed, PSQIA's intention is to facilitate a medical environment where well-intentioned professionals are able to candidly report, analyze, and share issues with each other in order to improve the health care system.

The PSQIA balancing concept between privileged information for quality improvement and disclosures for litigation provides a valuable lens to explore how compliance could be improved if a similar privilege were enacted. The increase in compliance facilitated by a privilege is likely to outweigh the need for the information to be discoverable in potential litigation. The following Part compares data collection under the PSQIA and compliance auditing under this analysis.

V. A CALL FOR REFORM: COMPARISONS BETWEEN PSQIA DATA COLLECTION AND COMPLIANCE AUDITS

The public policy reasoning for enacting the PSQIA and the subsequent improvement of patient safety provides a compelling argument to recognize a similar privilege for health care compliance audits. Before PSQIA was enacted, hospitals "historically took an adversarial and secretive approach to

¹⁵⁶ JC Amicus Brief, *supra* note 151, at 11 (citing 151 CONG. REC. 16,763, 16,892 (2005) (statement of Sen. Kennedy)).

¹⁵⁷ See Levy et al., *supra* note 140, at 411 (noting that "[n]otwithstanding the [PSQIA's] strong protection for [patient safety work product], statutory limitations curtail the types of records and information that qualify as PSWP" including "medical, billing, and discharge records, along with any other original patient or provider record").

lawsuits and error.”¹⁵⁸ But, after the PSQIA was implemented, providing confidentiality to internal error analysis promoted greater openness, transparency, and willingness to candidly discuss errors and areas of potential risk.¹⁵⁹

However, there are differences between compliance audits and patient safety data collection that present challenges to developing a compliance privilege. This Part will first discuss the differences between patient safety data collection under the PSQIA and compliance auditing and will then explore how the two systems are similar.

A. Overcoming Challenges: Why Differences Between Patient Safety Data Collection and Compliance Auditing Are Ultimately Immaterial

There are two distinct differences between patient safety privilege and the proposed compliance privilege. First, the PSQIA only recognizes a privilege for safety data that is submitted to a third-party patient safety organization. Second, health care entities generally assert the patient safety privilege in medical malpractice litigation, which is usually an individual, non-government plaintiff, while a compliance privilege would most likely be asserted in FCA actions where the government is plaintiff. This Part will conclude that the two differences may create challenges for establishing a compliance privilege, but those differences ultimately will not outweigh the predicted benefits of the compliance privilege.

1. Data Submission to Third Parties and the Utility of Data Aggregation

Although significant similarities exist between patient safety data collection and reporting and compliance auditing, the two self-scrutiny activities are not perfectly analogous. PSQIA privilege requires information to be sent eventually to a third party, a PSO, and does not protect reports that are collected only for internal purposes.¹⁶⁰ However, many states recognize an extended privilege to internal quality reports that are not sent to outside organizations.¹⁶¹ Additionally, patient safety data can be extremely useful in

¹⁵⁸ Joanna C. Schwartz, *A Dose of Reality for Medical Malpractice Reform*, 88 N.Y.U. L. REV. 1224, 1230 (2013).

¹⁵⁹ *Id.*

¹⁶⁰ See 42 U.S.C. § 299b-22(a)–(c) (2012); 42 C.F.R. §§ 3.204(a), 3.206(a) (2010).

¹⁶¹ See *supra* notes 148–49 and accompanying text.

the aggregate, especially for smaller hospitals that may not have enough data to easily identify patient safety trends.¹⁶²

It remains unclear whether compliance reporting will be useful in the aggregate, and therefore remains uncertain whether health care entities will greatly benefit from aggregate sharing. However, there would be an expected benefit if health care entities were able to candidly discuss problem-solving strategies with other health care entities in a protected environment. For example, if a health care entity's audit revealed a potential issue with AKS regarding durable medical equipment vendors, it is likely other health care entities may have experienced a similar issue and could give valuable advice on how to structure agreements to avoid AKS violations. Unfortunately, it is extremely unlikely that health care entities will engage discussions with other entities without legal protections in place. Providing a privilege to protect such information is likely to encourage health care entities to candidly discuss issues internally and with other entities and promote consistent interpretation of requirements and collaborative problem solving.

2. *The Government as Plaintiff and the Differences in Potential Litigation Recoveries*

The government as plaintiff is significant for two reasons. First, the FCA imposes considerable civil penalties that are not generally associated with patient safety events that may give rise to medical malpractice cases.¹⁶³ Second, the government may be more reluctant to expand privilege for compliance than it was for patient safety because a compliance audit privilege could impact the government's ability to bring FCA actions.¹⁶⁴

¹⁶² *Patient Safety Organization (PSO) Program: Frequently Asked Questions*, AGENCY FOR HEALTHCARE RES. & QUALITY, <https://www.pso.ahrq.gov/faq#BenefitstoHealthcareProviders> (last visited Feb. 15, 2015).

¹⁶³ Medical malpractice damages are often limited under state laws, while FCA violations automatically allow for treble damages. See Andrew W. Schilling, Ross E. Morrison & Michelle L. Rogers, *FCA Allows Treble Damages—'But Treble What?'*, LAW360 (Mar. 26, 2013, 11:22 AM), <http://www.buckleysandler.com/uploads/36/doc/FCA%20Allows%20Treble%20Damages.pdf> (discussing how the government calculates treble damages); Paul J. Passanante & Dawn Mefford, *The Effect of Tort Reform on Medical Malpractice*, 61 J. MO. B. 236, 241 (2005) (noting that while medical malpractice damages may vary from state to state, there are generally "three types of damages that may be awarded to a plaintiff . . . economic damages, non-economic damages and punitive damages").

¹⁶⁴ See Keith D. Barber, David B. Honig & Neal A. Cooper, *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*, 1 IND. HEALTH L. REV. 135, 161 (2004) (noting that "[o]ne of the most disturbing trends in false claims law for health care providers has been the filing of general allegations by qui tam relators who hope to create a case through the discovery process . . . which can include every claim submitted to Medicare or Medicaid over a six-year period").

Significant financial risk gives entities a strong incentive to be proactive in preventing violations, which may not be as significant in individual medical malpractice cases.¹⁶⁵ One could argue that the financial risk imposed by the FCA is already adequate encouragement for entities to be compliant. For example, in medical malpractice cases, the mean award ranges from \$199,000 to \$262,000, subject to whether state law imposes caps on noneconomic damages.¹⁶⁶ In comparison, mandatory per-claim penalties for an FCA violation can mean that “one error or misinterpretation can result in millions of dollars in penalties under the Act.”¹⁶⁷ This financial risk provides a significant incentive for health care entities to investigate possible violations.¹⁶⁸

However, while the threat of litigating a FCA case does provide a financial incentive for hospitals to be compliant, other financial factors may hinder compliance efforts. Given that many hospitals operate on a 2% profit margin,¹⁶⁹ a risk analysis may show that the cost to develop more robust internal compliance auditing systems does not outweigh the risk of litigating, especially if the audit findings will be discoverable and possibly used against them. This analysis may ultimately encourage hospitals to spend their resources in other areas.

The other reason that the government as plaintiff may hinder Congress from recognizing a compliance audit privilege is the government’s interest in settling or litigating against health care entities in FCA actions. Unlike medical malpractice cases, where the government has no financial interest, the government has a significant financial interest in FCA actions. The government’s financial interest could impede efforts to recognize a compliance privilege if the government views the compliance privilege as a barrier to bring suit against FCA violators.

Conversely, the government also has a financial incentive to *promote* internal compliance auditing and continued improvements to system-wide

¹⁶⁵ See Schilling et al., *supra* note 163.

¹⁶⁶ Ronen Avraham, *An Empirical Study on the Impact of Tort Reforms on Medical Malpractice Settlement Payments*, 36 J. LEGAL STUD. S183, S210 (2007) (“[T]he mean (median) award of [medical malpractice] cases not subject to caps is \$262,000 (\$132,000), whereas the mean (median) award of [medical malpractice] cases subject to caps is only \$199,000 (\$84,000).”).

¹⁶⁷ Stephanie L. Trunk, Note, *Sounding the Death Toll for Health Care Providers: How the Civil False Claims Act Has a Punitive Effect and Why the Act Warrants Reform of Its Damages and Penalties Provision*, 71 GEO. WASH. L. REV. 159, 164 (2003).

¹⁶⁸ *Id.*

¹⁶⁹ *Improving Operating Margins Requires More Than Cost Reduction*, VETERANS HEALTH ADMIN., <https://www.vha.com/expertise/Pages/OperatingMargins.aspx> (last visited Feb. 29, 2016).

compliance. Many chief compliance officers acknowledge that, although compliance should be “everyone’s responsibility,” many individuals are very fearful to report any potential violations.¹⁷⁰ Greater privilege may lead to greater compliance, demonstrated by the PSQIA privilege, and thus fewer violations of federal regulations.

However, as likely as the increase in compliance prompted by the greater privilege, some believe that greater privilege may lead to greater noncompliance, if hospitals believe they can “hide” behind the privilege and intentionally defraud the government.¹⁷¹ While this result is possible, it is unlikely for several reasons. First, similar to PSQIA, the compliance audit privilege would not extend to the underlying facts and data. Therefore, any repayment data or medical records would still be discoverable. Second, this privilege would not interfere with current government auditing and required data reporting; the only information this privilege would protect from government interference or discovery would be investigations conducted for the purpose of improving quality and compliance. Thus, narrowing the privilege to encompass just compliance audits may be sufficient to prevent protection of purposeful fraud or promote negligent behaviors.

B. Justifying a New Privilege: Similarities Between Patient Safety Data Collection and Compliance Auditing

Although the incentives for compliance may be different from a patient safety evaluation system, there are many structural similarities between the two programs that suggest many of the benefits associated with the PSQIA privilege would also be seen in a compliance privilege. This section predicts several situations where a compliance audit privilege could improve regulatory compliance.

1. Events with Concurrent Patient Safety and Compliance Implications

The same event often carries both patient safety and compliance implications. For example, a facility may discover that a patient does not have a suspected diagnosis. Billing codes are established through a payment system called “diagnostically related groups” (DRGs), which CMS reimburses through the same bundled payments for each patient with the same DRG for all

¹⁷⁰ STATE OF COMPLIANCE SURVEY, *supra* note 122, at 3.

¹⁷¹ See Kaisersatt, *supra* note 44, at 421–22.

services rendered.¹⁷² As a result, if a patient's DRG is assigned, billed, and collected, but a later compliance review determines the wrong DRG was used, the entity must refund CMS for payment for services rendered under the incorrect DRG and re-bill CMS under the correct DRG.¹⁷³ Since this situation impacts the patient's quality of care and billing practices, it has patient safety implications as well as compliance issues.

Similarly, overlap of compliance and safety issues occurs when a provider bills for services beyond their scope of practice.¹⁷⁴ If providers are performing services they are not legally empowered to perform, there could be patient safety implications.¹⁷⁵ A health care entity should investigate the scope of practice violations to improve safety, and also to investigate whether refunds to the government are needed if such improper services were previously billed to CMS. Even if the service was properly performed, there could still be a FCA violation if the provider was outside his or her scope of practice.¹⁷⁶

It is unreasonable to suggest that the same investigation should be protected for a patient safety implication but not privileged for a compliance implication. This incongruity will likely promote fear and confusion among health care providers over what type of investigation is or is not protected and is therefore likely to discourage robust investigations.

2. *Reporting Near Misses*

A PSQIA situation previously discussed encouraged health care providers to report "near misses."¹⁷⁷ Because of the privilege, providers were willing to report a misplaced decimal point when entering a medication order, even

¹⁷² See Uwe E. Reinhardt, *Medicare's Soviet Label*, N.Y. TIMES: ECONOMIX (Nov. 12, 2010, 6:00 AM), <http://economix.blogs.nytimes.com/2010/11/12/medicares-soviet-label/>.

¹⁷³ See Ruth Orcutt, *Common Coding Errors and How to Prevent Them*, CLINICAL-INSIGHTS (June 2009), <http://www.clinical-insights.com/resources-June09CodingErrors.html>.

¹⁷⁴ Generally, scope of practice refers to the "legislatively-defined spheres" of services and treatments each type of health care provider is legally authorized to practice. Barbara J. Safriet, *Closing the Gap Between Can and May in Health-Care Providers' Scopes of Practice: A Primer for Policymakers*, 19 YALE J. ON REG. 301, 303 (2002).

¹⁷⁵ See generally AM. ASS'N OF CRITICAL-CARE NURSES, AACN SCOPE AND STANDARDS FOR ACUTE CARE NURSE PRACTITIONER PRACTICE 9 (Linda Bell ed., 2012) (noting that a "consistent definition for the [scope and standards for nurses] provides evidence to the public that the candidate meets established standards of quality and patient safety, which includes demonstrated competence for advanced practice").

¹⁷⁶ See Gretchen Harper, *Trust Me I'm a Doctor: The Struggle over Scope of Practice and Its Effect on Health Care Fraud and Abuse*, 15 DEPAUL J. HEALTH CARE L. 237, 245 (2013).

¹⁷⁷ See *supra* note 152 and accompanying text.

though the issue was corrected before any potential safety event happened.¹⁷⁸ Without reporting the problem, the same error could reoccur; however, now the hospital can submit the near miss without fear of creating evidence that could be used against the hospital.¹⁷⁹ From this kind of safety data now being collected, such a hospital can create recommendations, protocols, or feedback on the best way to avoid this problem in the future.

This situation also occurs in the compliance context. One can easily imagine a situation where unintentional upcoding almost occurs, but a coder catches the problem before anything is billed.¹⁸⁰ Currently, upcoding—especially in long-term care—has been the focus on many *qui tam* lawsuits.¹⁸¹ Other similar errors could include writing the incorrect weight for a patient and thus miscalculating the pain medicine or chemotherapy dosage. It is reasonable to suggest these coding or miscalculation problems could be similar to the medication decimal error in the above PSQIA example,¹⁸² and that a similar PSQIA privilege for reporting this compliance information would be beneficial to the health care entity and to ensure the government continues to receive proper payment.

3. *Never Events*

Another situation where a compliance privilege also would promote open communication and in depth investigational analysis when conducting a root cause analysis for a “never event.”¹⁸³ Never events are serious patient safety

¹⁷⁸ See *supra* note 152 and accompanying text.

¹⁷⁹ See *supra* note 152 and accompanying text.

¹⁸⁰ Upcoding is when an inaccurate billing code is assigned to a medical procedure or treatment, which results in an improper, usually higher, government reimbursement. Leemore Dafny & David Dranove, *Regulatory Exploitation and Management Changes: Upcoding in the Hospital Industry*, 52 J.L. & ECON. 223, 224 (2009).

¹⁸¹ OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., OEI-04-10-00180, CODING TRENDS OF MEDICARE EVALUATION AND MANAGEMENT SERVICES 13–15 (May 2012), <http://oig.hhs.gov/oei/reports/oei-04-10-00180.pdf>. The report does not conclude that these billings are all false claims, but the increase in billing higher-level codes is suspect.

¹⁸² In a broader context, upcoding can “move beyond simple billing errors to create actual overpayments due to improper billing methods, possibly due to [electronic medical record] cloning or inappropriate use of templates.” Robert A. Wade & Alex T. Krouse, *EHRs, Upcoding, Overpayments, and the False Claims Act—Understanding the Risks*, 10 ABA HEALTH ESOURCE, http://www.americanbar.org/publications/aba_health_esource/2013-14/november/ehrs.html (last visited Feb. 15, 2015); see also *United States ex rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, No. 11-CV-00892, 2013 WL 1307013 (E.D. Wis. Mar. 28, 2013).

¹⁸³ A root cause analysis is a method of problem solving that attempts to identify the underlying causes that once removed, prevents the ultimate undesirable event from recurring. RCA is based on process improvement and problem solving techniques. See, e.g., *What is Root Cause Analysis (RCA)?*, AM. SOC’Y FOR

events that should never occur if proper preventative measures had been implemented, such as a wrong-side surgery.¹⁸⁴ To find out how such an event happened, what went wrong,¹⁸⁵ and to develop strategies to prevent the problem from reoccurring, it is best to have a privilege to investigate. Because hospitals cannot bill for never events,¹⁸⁶ payment would have to be reimbursed if it had previously been billed, thus creating a potential compliance issue.

These examples demonstrate that privilege promotes a culture of compliance, resulting in an increased likelihood that a health care entity will encourage people to report potential or known compliance violations. Once reported, such a privilege not only makes that investigation more likely to occur, but also makes it more likely that the investigation will be thorough, honest, and effective. That investigation also will reveal if repayment to CMS might be needed. While these situations are only hypothetical, it is reasonable to predict that providing a privilege to certain types of compliance auditing activity would encourage health care entities to conduct more systematic reviews of their activities to ensure regulatory compliance. Moreover, individuals may be more willing to share information with the compliance department if they know that those discussions are privileged and the individual can avoid being labeled a troublemaker or whistleblower.

VI. PROSPECTIVE OBSTACLES FOR COMPLIANCE PROGRAMS

As a practical matter, employees and health care providers are likely to engage more often with compliance officers than with in-house legal counsel.¹⁸⁷ Thus, the issue becomes what compliance officers are empowered to do with compliance information shared with their department by personnel. As previously discussed in Part V, a privilege will likely promote greater

QUALITY, <http://asq.org/learn-about-quality/root-cause-analysis/overview/overview.html> (last visited Feb. 15, 2015).

¹⁸⁴ *Patient Safety Primers: Never Events*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://psnet.ahrq.gov/primer.aspx?primerID=3> (last updated Dec. 2014).

¹⁸⁵ Root cause analyses discourage focusing on what individual people may have done wrong because often it is the processes that are broken. See Fay A. Rozovsky, *Response to the Keynote: Who Cares About Quality Measurement?*, AHILA-PAPERS P06170104 (AHILA Seminar Materials June 18, 2001). By understanding how processes can be improved, the entire system is strengthened and less vulnerable to human error. *Id.*

¹⁸⁶ NAT'L BUS. COAL. ON HEALTH, HEALTH CARE PURCHASER TOOLKIT: HOSPITAL-ACQUIRED CONDITION PAYMENT POLICY 3 (2009) (noting a "Medicare policy in which it will no longer elevate payment to reimburse for [never events]").

¹⁸⁷ See FLEPS, *supra* note 11.

openness and information sharing, but a compliance privilege may also create additional dilemmas.

For example, one could imagine a situation where a potential whistleblower calls a compliance hotline to report a possible violation, the compliance office analyzes the complaint, and then decides to hire outside counsel to do an investigation. The outside counsel conducts an audit and concludes the possible violation is not a risk and provides a report to the hospital.

Current law would likely uphold attorney–client privilege for this report because the healthcare entity sought legal advice from an attorney.¹⁸⁸ However, there are likely to be situations where the hospital would want to share the good outcome and due diligence with the government and thus waive the privilege for this document. This would be considered a subject matter waiver.¹⁸⁹ In a subject matter waiver, when an entity waives privilege, it is unclear how broad that waiver is.¹⁹⁰ This uncertainty creates a dilemma for compliance auditing: if health care entities have a privilege for compliance audits, sharing this information with the government, even if sharing may be beneficial for the health care entity, could risk eliminating protection for other privileged documents for which the entity had no intention of waiving privilege. If courts interpret subject matter waiver broadly, subject matter waivers may be so risky for entities that it could benefit the entity *not* to have a privilege for compliance reports. If there is not a privilege, entities could share their non-privileged compliance reports with the government and not risk accidentally “opening the door” and thus waiving privilege on other currently protected documents.¹⁹¹

¹⁸⁸ See, e.g., *id.* § 4:4-3.

¹⁸⁹ See, e.g., Ted S. Helwig & David S. Slovick, *The Dilemma Remains: The Collateral Effect of Disclosing Attorney-Client Privileged Communications and Attorney Work Product to Government Agencies*, 26 FUTURES & DERIVATIVES L. REP., May 2006, at 1, 1 (“Voluntary disclosure to a regulatory or criminal authority may trigger serious consequences regarding the waiver of the privilege and the protection of pending or anticipated private, civil litigation.”).

¹⁹⁰ See, e.g., *id.* (“A dispute exists . . . over the viability of the so-called ‘selective waiver’ doctrine . . .”).

¹⁹¹ “Opening the door” includes the possibility of waiving the compliance privilege to other documents about the same subject matter, and also the possibility of opening the door to documents of the same subject matter that are currently protected under privileges other than a compliance privilege.

Unfortunately, the proposed compliance privilege discussed here does not provide an easy solution for this quandary. One solution for a subject matter waiver protection could be to explicitly legislate that waiving privilege on a self-evaluative work product for compliance auditing does not waive any other privileges. However, sole reliance on the language of a statute is risky because statutes will always have some degree of ambiguity and will be subject to court interpretation.¹⁹² While not explicitly discussing subject matter waiver, the PSQIA does permit patient safety work product to be disclosed in certain circumstances without losing its privilege.¹⁹³ These circumstances include voluntary disclosures to an accrediting body or to a government agency.¹⁹⁴ Therefore, for a compliance privilege, Congress could explicitly legislate to protect against subject matter waivers and thus fully recognize the importance and benefits of such a compliance privilege.

CONCLUSION

The recent proliferation of regulations and the government's aggressive enforcement of those regulations against health care entities create strong incentives for health care entities to become and to remain compliant with the law. However, aggressive enforcement against these entities does not fully ameliorate the problem of noncompliance because unintentional FCA violations are better addressed through prevention, rather than punishment. Until Congress acts, health care entities will continue to operate in an environment of fear and uncertainty, which ultimately weakens the health care system as a whole. Therefore, Congress must respond by enacting a limited federal privilege for ongoing compliance audits. Such a privilege will provide

¹⁹² See *supra* note 149 and accompanying text.

¹⁹³ 42 C.F.R. § 3.206(b) (2015).

¹⁹⁴ *Id.* § 3.206(b)(7)–(8).

protection for robust compliance auditing, which will serve to create a culture of openness within an individual health care entity and promote an efficient, affordable, and effective national health care system.

CAITLIN PARDUE*

* Emory University School of Law, J.D. Candidate, 2016; Managing Editor, *Emory Law Journal*; B.A.: double major in Public Policy and Psychology, University of North Carolina at Chapel Hill, Class of 2011. I am thankful to my comment advisor, Professor Joanna Shepherd, for her thoughtful feedback and invaluable reminders not to lose sight of the forest for the compliance-laden trees. Her mentorship allowed me to explore my evolving interest for health law early in my legal studies as a research assistant, which has been an invaluable component to my ongoing health law education. I am also profoundly grateful to Kathy Steuer, Senior Associate Counsel at St. Jude Children's Research Hospital, for her guidance throughout this Comment-writing experience; her enthusiastic support and mentorship has significantly enriched and shaped my law school career as someone who exemplifies the kind of lawyer I strive to become. Many thanks to Professor Ani Satz as well for her comments and suggestions. I would also like to thank Rebecca Hall and all the editors of the *Emory Law Journal*, for their unflagging attention to detail and thoughtful feedback. Special thanks to Matt Johnson for his leadership and support. Finally, I would like to thank my brother for his early morning phone calls—even when he calls before I've had my coffee—to discuss the latest health-related current events, and my parents for their unwavering support and love.