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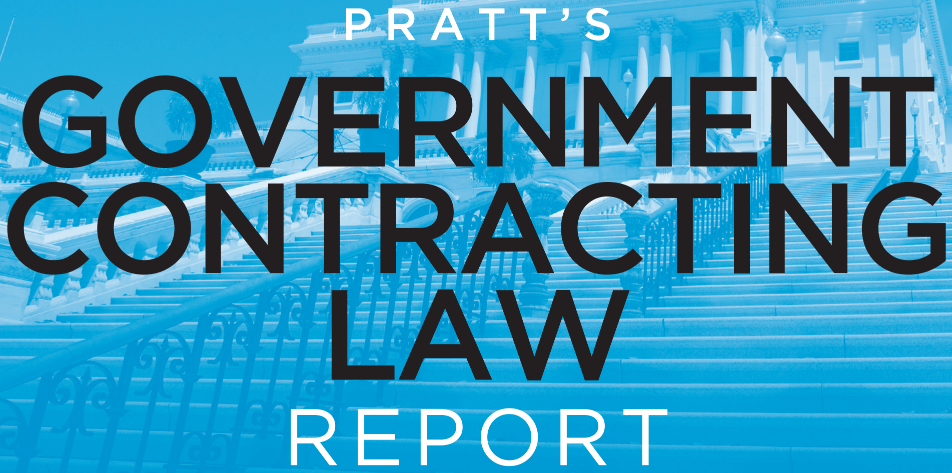

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Understanding When an Overpayment Can Result in False Claims Liability and Why Current Court Precedent and Regulatory Guidance is Mistaken—Part II

By Robert S. Salcido*

One of the most vexing issues confronting any health care entity is the determination of when precisely it has a duty to disclose an "overpayment" to the government. In this two-part article, the author discusses the issue and why court precedent and regulatory guidance is mistaken. The first part, which appeared in the March 2016 issue of Pratt's Government Contracting Law Report, *discussed Congress' 2009 False Claims Act amendments. This second part explores the Affordable Care Act amendments and relevant regulatory and case law developments.*

AFFORDABLE CARE ACT AMENDMENTS

Consistent with the 2009 False Claims Act ("FCA") revisions, Congress, in 2010, in the Patient Protection and Affordable Care Act,[1] imposed additional duties on health care providers and suppliers to report and remit overpayments within 60 days of when those overpayments were "identified." Specifically, the provision requires the person to report and return the overpayment "by the later of (A) the date which is 60 days after the date on which the overpayment was identified or (B) the date any corresponding cost report is due, if applicable."[2] Under the ACA, any overpayment retained after this deadline is an "obligation" for purposes of the FCA, and hence, can subject the person to FCA treble

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[1] Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) [hereinafter, "ACA"]. Section 6402 of the ACA established a new Section 1128J(d) of the Social Security Act titled "Reporting and Returning of Overpayments." This provision is codified at 42 U.S.C. § 1320a-7k(d).

[2] The statute defines an "overpayment" as "any funds that person receives or retains under title XVIII [Medicare] or XIX [Medicaid] to which the person, after applicable reconciliation, is not entitled under such title." 42 U.S.C. § 1320a-7k(d)(4)(B).

damages and civil penalties.[3]

Oddly, although, as noted in detail above, the FCA standard regarding overpayments is "knowingly and improperly," this provision contains only a definition of "knowingly" which it defines as having "the meaning given those terms in section 3729(b) of title 31."[4] Equally oddly, although this subsection defines the words "knowing and knowingly," the subsection itself, addressing "Reporting and returning of overpayments," never uses those words except in the definition.[5]

REGULATORY AND CASE LAW DEVELOPMENTS

The prior sections have developed how the FCA's overpayment provision contains an overt "knowingly and improperly" knowledge standard, while the FCA generally contains merely a reckless disregard and deliberate ignorance knowledge standard. This section will describe why it matters that Centers for Medicare & Medicaid Services ("CMS") and courts apply the correct knowledge standard—the knowing and improper standard, not the reckless disregard and deliberate ignorance standard—when construing the FCA's overpayment provision.

Why Applying the Correct Knowledge Standard Matters

There are different gradations of knowledge that Congress establishes based upon the conduct it intends to regulate. For the FCA's reverse false claim provision, as demonstrated, Congress intended a higher knowledge standard apply. This has significant practical importance in determining whether there is actual FCA liability related to the retention of an overpayment.

Knowingly and Improperly

As noted, Congress was clear that it used the standard "knowingly and improperly" as a term of art, to proscribe conduct that is "*malum in se*," or "inherently wrongful," or "willful" and where a person "employed means that

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[3] 42 U.S.C. § 1320a-7k(d)(3) ("Enforcement—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in Section 3729(b)(3) of title 31").

[4] *Id.,* § 1320a-7k(d)(4)(A); *see also* 77 Fed. Reg. 9179 (Feb. 16, 2012) ("Section 1128J of the Act provides that the terms 'knowing' and 'knowingly' have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). The statutory text, however, does not use this phrase other than in the definitions").

[5] *See* 42 U.S.C. § 1320a-7k(d).

are inherently tortious or illegal."[6] When courts have considered what conduct constitutes such willful conduct, such as when considering whether defendants violated the Anti-Kickback Statute ("AKS"), they have required the government to establish that the defendant knew that its conduct was wrongful.[7]

Reckless Disregard and Deliberate Ignorance

Unlike a willful standard, or *malum in se* standard, under both a reckless disregard and deliberate ignorance standard, the person does not consciously need to know that the conduct is wrongful. For example, in FCA actions, courts have instructed jurors that to find that a defendant acted with reckless disregard, they must find that the defendant's conduct amounted to a form of aggravated negligence such as gross negligence plus.[8] Thus, under these circumstances, the

[6] *See* 155 Cong. Rec. S4539–40 (2009); *see also* S. Rep. 10 at 15, *reprinted in* 2009 U.S.C.C.A.N., at 442.

[7] *See, e.g., United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013); *United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998) (upholding AKS jury instruction that "[t]he word willfully . . . means the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law"); *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996) (affirming AKS jury instruction that "the word 'willfully' means unjustifiably and wrongfully, known to be such by the defendant"); *see also United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000) (noting that neither the government nor defendant objected to AKS jury instruction defining willfulness as: "An act is done willfully if it is done voluntarily and purposely and with the specific intent to do something the law forbids, that is, with a bad purpose either to disobey or disregard the law. A person acts willfully if he or she acts unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. Thus, in order to act willfully as I have defined that term, a person must specifically intend to do something the law forbids, purposely intending to violate the law"); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (affirming an AKS jury instruction that willfully "means that the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law"); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (upholding AKS jury instruction explaining that "[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that law forbids").

[8] For FCA jury instructions regarding reckless disregard, *see, e.g., United States v. Science Applications Int'l Corp.*, No. CA04-1543, ECF No. 161 at 16 (D.D.C. Feb. 5, 2009) ("I also instructed you that the term 'knowingly' includes acting in 'reckless disregard' or an act's truth or falsity. For purposes of the False Claims Act, reckless disregard can be equated with 'an extreme version of ordinary negligence' or 'gross negligence plus' "); *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, No. 95-1231 (D.D.C. May 4, 2007) ("I also instruct you that the term knowingly includes acting in reckless disregard of an act's truth or falsity. The term reckless means gross negligence plus. If a defendant submitted a claim, or caused a claim to be submitted, without properly considering the claim's truth or falsity, that defendant may be found to have acted in reckless disregard of its truth or falsity"); *United States ex rel. Grynberg v. The*

person is reckless in not finding the relevant facts when acting with gross negligence plus (extreme carelessness), but does not need to have actual knowledge that the conduct is wrongful.

Similarly, as to deliberate ignorance, courts have instructed jurors that, to find that a defendant acted with deliberate ignorance, they must find that the defendant acted with "deliberate blindness" or "willful blindness" or "deliberately closed its eyes" as to what otherwise should be obvious to the defendant.[9] Thus under these circumstances, the person is consciously aware ("*deliberately* ignorant") that material facts are unknown, but does not need to have actual knowledge that the conduct is wrongful. Thus, the fundamental difference between a "knowing and improper" standard and a reckless disregard/deliberate ignorance standard is whether the person actually knew the conduct was inherently wrongful.

Regulatory and Legal Background Interpreting the FCA's Overpayment Provision

CMS, in its proposed rule implementing the ACA, did not attempt to apply

BOC Grp., No. 97-D-2422 (D. Col. Apr. 5, 2004) ("Instruction no. 28. Under the False Claims Act, knowledge may be established if the defendant acted with reckless disregard of the truth or falsity of a statement. The term 'reckless disregard' is an aggravated form of gross negligence of, quote, gross negligence plus, unquote. Stated differently, the term, quote, reckless disregard, unquote, means a lack of care which is so pronounced as to be more than grossly negligent").

[9] For FCA jury instructions regarding deliberate ignorance, *see, e.g., United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, No. 3:05-2858, ECF. No. 575 at 82 (D.S.C. Aug. 16, 2010) ("Plaintiff can prove deliberate ignorance through proof that a defendant deliberately closed its eyes to what would otherwise have been obvious to the defendant"); *United States v. Science Applications Int'l Corp.*, No. CA04-1543, ECF No. 161 at 16 (D.D.C. Feb. 5, 2009) ("A finding that SAIC purposely avoided learning all the facts or suspected a fact but refused to confirm it also constitutes deliberate ignorance. Stated another way, SAIC's knowledge of a fact may be inferred from willful blindness to the existence of the fact. It is entirely up to you as to whether you find any deliberate closing of the eyes and the inference to be drawn from any such evidence"); *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, No. 95-1231 (D.D.C. May 4, 2007) ("Plaintiffs can prove deliberate ignorance through proof that a defendant deliberately closed its eyes to what would otherwise have been obvious to the defendant. A finding that a defendant purposely avoided learning all the facts or suspected a fact but refused to confirm it, also constitutes deliberate ignorance. Stated another way, a defendant's knowledge of a fact may be inferred from willful blindness to the existence of the fact. It is entirely up to you as to whether you find any deliberate closing of the eyes and the inference to be drawn from any such evidence"); *United States ex rel. Grynberg v. The BOC Grp.*, No. 97-D-2422 (D. Col. Apr. 5, 2004) ("Instruction no. 27. Deliberate ignorance means that BOC closed its eyes to what would have otherwise been obvious to BOC. While deliberate ignorance on the part of BOC cannot be established merely by a demonstration that BOC was negligent, careless, or foolish, knowledge in the form of deliberate ignorance can be inferred if BOC deliberately blinded itself to the existence of a fact").

the correct "knowing and improper," *malum in se*, inherently wrongful standard, but, instead, a purported reckless disregard or deliberate ignorance standard, which bordered on asserting that mere negligence could constitute an FCA violation, directly contrary to congressional intent. Courts, thus far, have similarly failed to apply the correct knowledge standard to the FCA's overpayment provision.

CMS Applies the Wrong Knowledge Standard in the Overpayment Provision

On February 16, 2012, CMS published a proposed rule implementing the ACA's provision mandating that an overpayment be reported and returned within 60 days of when the overpayment was identified or the date any corresponding cost report was due, if applicable.[10] In proposing the Rule, CMS made two significant mistakes: (1) it misconstrued the overpayment provision's knowledge element; and (2) as a consequence, when it purported to provide concrete examples of alleged violations, it produced a literal hodgepodge of imprecise examples ranging from conduct that would appropriately constitute "knowing and improper" conduct under the correct standard to examples that would only satisfy a mere negligence threshold. Merely negligent conduct is not even actionable under the FCA's general knowledge standard, let alone the heightened knowledge standard governing the FCA's overpayment provision.[11]

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[10] *See* 77 Fed. Reg. 9179 (Feb. 16, 2012).

[11] The FCA, everyone would agree, does not reach merely negligent conduct. *See, e.g., United States ex rel. Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015) ("Congress did not intend to turn the False Claims Act, a law designed to punish and deter fraud . . . into a vehicle either punish[ing] honest mistakes or incorrect claims submitted through mere negligence or imposing a burdensome obligation on government contractors rather than a limited duty to inquire") (internal quotations and citations omitted); *United States ex rel. Owens v. First Kuwaiti*, 612 F.3d 724, 726–28 (4th Cir. 2010) ("Congress . . . made plain its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence" and noting that "Congress crafted the FCA to deal with fraud, not ordinary contractual disputes. The FCA plays an important role in safeguarding the integrity of federal contracting, administering strong medicine in situations where strong remedies are needed. Allowing it to be used in run-of-the-mill contract disagreements and employee grievances would burden, not help, the contracting process, thereby driving up costs for the government and, by extension, the American public"); *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 338 (5th Cir. 2008) (noting that the FCA's "*mens rea* requirement is not met by mere negligence or even gross negligence" and citing to *United States v. Krizek*, 111 F.3d 934, 941–42 (D.C. Cir. 1997) that at least "aggravated gross negligence" or an "extreme version of ordinary negligence" is necessary under the FCA"); *Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002) ("innocent mistakes and negligence are not offenses under the Act") (internal quotation and citations omitted); *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001) ("the requisite intent is the knowing presentation of what is known to be false as opposed to negligence or innocent mistake") (internal

In construing the overpayment knowledge element, CMS proposed that an overpayment is identified when a "person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment."[12] The basis for this conclusion is that CMS believed that "Congress' use of the term 'knowing' in the ACA was intended to apply to determining when a provider or supplier has identified an overpayment."[13]

CMS asserted that a "reckless disregard" or "deliberate ignorance" standard is appropriate, because it will provide an incentive to providers and suppliers to exercise "reasonable" diligence:

> In some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment. On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance to whether it received such an overpayment. For example, a provider that receives an anonymous compliance hotline telephone complaint about a potential overpayment has incurred an obligation to timely investigate that matter. If the provider diligently conducts the investigation, and reports and returns any resulting overpayments within the 60-day reporting and repayment period, then the provider would have satisfied its obligations under the proposed rule. If, however, the provider fails to make any reasonable inquiry into the complaint, the provider may be found to have acted in reckless disregard or deliberate ignorance of any overpayment.[14]

Remarkably, CMS noted that "[w]hen *there is reason to suspect* an overpay-

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quotations and citations omitted); *Hindo v. Univ. of Health Sciences, The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) ("[i]nnocent mistakes or negligence are not actionable under [§ 3729]").

[12] 77 Fed. Reg. at 9182.

[13] *Id.*

[14] *Id.* at 9182. *See also id* ("We believe defining 'identification' in this way gives providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition, some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research").

ment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may be found to have acted in reckless disregard or deliberate ignorance of any overpayment."[15]

CMS' proposed knowledge standard is defective in two respects. First, it never tries to apply the actual knowledge standard that Congress created or provide examples, in light of that standard, of when an individual or entity would possess sufficient knowledge to act "knowingly and improperly" in not conducting an additional investigation. Second, and more significantly, unwittingly or not, it conflates a reckless disregard/deliberate ignorance standard with a mere negligence standard.[16]

Leaving aside CMS' errors in legal interpretation, the examples it provides regarding potential violations of the FCA overpayment provision do provide some practical guidance regarding what conduct would potentially constitute a violation of the FCA overpayment provision under a correct analysis of its knowledge standard.

As noted previously, to constitute a "knowing and improper" retention of an overpayment, the person must know that it is inherently wrongful to retain an overpayment under the circumstances. That is the trigger Congress set for the person to be duty-bound to conduct additional investigation. Under this test, the following examples that CMS provided would likely satisfy the actual standard that Congress created:

- "A provider of services or supplier reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.
- "A provider of services or supplier learns that a patient death occurred prior to the service date on a claim that has been submitted for payment."
- "A provider of services or supplier performs an internal audit and discovers that overpayments exist."[17]

Under these examples, CMS is clearly correct under even the correct

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[15] *Id.*

[16] For example, stating that a person has a duty to investigate further whether there is an overpayment merely if one has "reason to suspect" an overpayment appears to indicate that one will be liable for merely negligent conduct—that is not being reasonable in acting upon information that there may be an overpayment—which is directly inconsistent with Congress' intent in creating a "knowing and improper" standard and also directly inconsistent with the FCA, which, as noted, everyone agrees could never reach merely negligent conduct.

[17] Each of these bullets is at 77 Fed. Reg. at 9182.

"knowing and improper" standard. If a provider or supplier conducts a review and concludes that claims were actually miscoded, or services were billed when no services were provided, or an internal audit identifies actual overpayments, then it would be inherently wrongful and *malum in se* at that point for the entity to retain governmental funds to which it is not entitled, and that entity could be liable if those funds were not reported and repaid within the time period allotted in the statute.

However, other examples, which CMS states could trigger liability, are clearly wrong, because they would transform the FCA, a statute mandating the award of treble damages and civil penalties, and requires a knowing fraud into a statute that, contrary to congressional intent, reaches merely negligent conduct. For instance, CMS provided the following problematic examples and commentary:

- "[A] provider that receives an anonymous compliance hotline telephone complaint about a potential overpayment has incurred an obligation to timely investigate that matter . . . If . . . the provider fails to make any reasonable inquiry into the complaint, the provider may be found to have acted in reckless disregard or deliberate ignorance of any overpayment."
- "When there is reason to suspect an overpayment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may be found to have acted in reckless disregard or deliberate ignorance of any overpayment."
- "A provider of services or supplier is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry."
- "A provider of services or supplier experiences a significant increase in Medicare revenue, and there is no apparent reason—such as a new partner added to a group practice or a new focus on a particular area of medicine—for the increase. Nevertheless, the provider or supplier fails to make a reasonable inquiry into whether an overpayment exists."[18]

In each bullet, CMS does not provide enough information to address the ultimate question which is whether under the circumstances, it would be "inherently wrongful" for the provider or supplier to fail to conduct a further review. Under the first bullet, under many circumstances, it would not be inherently wrongful for a provider or supplier *not* to conduct an additional review. For example, if you have a hospital system that has a financial

[18] Each of these bullets is at 77 Fed. Reg. at 9182.

relationship with a thousand physicians and you receive a hotline complaint that an unnamed physician is upcoding, it would not be reasonable for a compliance department to conduct any inquiry, because there is no viable lead to pursue. Indeed, under these circumstances, where would you even start to conduct a review? Under these circumstances, no additional review would be needed, let alone it being inherently wrongful to fail to conduct an additional review.

The second, third, and fourth bullets are equally wrong. The second bullet inexcusably conflates what appears to be a negligence standard—having "a reason to suspect"—into a "reckless disregard" or "deliberate ignorance" standard without understanding that each knowledge standard is an entirely different term of art, with its own separate body of case law, which reaches entirely different types of conduct and has entirely separate jury instructions describing the standard.

As to the third and fourth bullets, much turns again on the details regarding what was disclosed to the provider and supplier when the government agency informed the provider or supplier of a "potential" overpayment or understanding what may have resulted in an unexpected spike in revenue. For example, it may be clear to the institution that the government's evaluation, which frequently occurs, is simply wrong and additional review is not necessary, and the institution would be satisfied to defend against any future governmental action if the government later concludes that the "potential" overpayment is an actual overpayment and undertakes some action to recoup the funds. Additionally, there are a multitude of reasons that an institution may experience a spike in revenue, and, offhand, it is difficult to discern why an institution should be subjected to FCA liability if it does not undertake a detailed review if this occurred. But, in any event, again, more fundamentally, these examples are asking the wrong question. Under the law, the question is whether it would be "inherently wrongful" for the provider or supplier to not conduct a further review under the circumstances, and CMS' examples do not provide sufficient facts from which one can reasonably conclude that it would be inherently wrongful not to conduct additional review under the proffered facts.[18.1]

Court Precedent Has Incorrectly Construed the FCA Overpayment Provision

Equally alarming, court precedent has incorrectly construed the FCA

[18.1] On February 12, 2016, the Centers of Medicare & Medicaid Services issued a final rule governing Medicare overpayments that is relevant to the author's analysis on pp. 127-131. *See* 81 Fed. Reg. 7654 (Feb. 12, 2016).

overpayment provision, based in part on CMS' mistaken regulatory interpretation. For example, in *United States ex rel. Kane v. Healthfirst, Inc.*,[19] a district court found that, for purposes of defendants' motion to dismiss, the government adequately pleaded that defendants avoided returning the overpayments, because the complaint alleges that a software glitch was brought to defendants' attention by at least December 2010. Although the defendants tasked the relator with investigating the scope of the issue, when he presented them with a list of potentially affected claims, he was fired, and the government alleges that defendants did nothing further with his analysis and although they repaid certain claims that were specifically brought to their attention by the Comptroller, they neglected to repay more than three hundred claims until they received the government's Civil Investigative Demand in June 2012.[20]

The district court, in reaching this conclusion, failed to apply the FCA's actual "knowing and improper" standard related to overpayments but instead applied the FCA's general "knowing" standard that applies to other provisions in the FCA.[21] Because, as noted, the case was merely at the pleading stage, the court had to assume the allegations in the complaint to be true. But if discovery validates defendants' position that the relator did nothing more than identify potential overpayments and that approximately half of all claims the relator identified as potential overpayments ultimately did not constitute overpayments, and the court applies the correct knowing and improper standard, rather than the FCA's general knowledge standard, the defendants can potentially prevail under these facts at summary judgment.

However, the court's failure to apply the correct standard has important implications for the health care industry, because it could potentially lead to a body of case law applying the incorrect standard, which would inevitably lead to more FCA actions and cause health care entities to markedly expand their compliance departments and, under these circumstances, divert needed resources from actual patient care.

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[19] No. 11 Civ. 2325 (ER), 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

[20] *Id.* at *55.

[21] *Id.* at *57–59. *See also United States ex rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, No. 2:11-cv-00892-LA (E.D. Wis. Mar. 28, 2013). There, the relator alleged that the defendant clinic conducted audits that revealed that physicians were upcoding consultation services at a high rate and did nothing to determine whether nonaudited services were also upcoded. The district court ruled that the relator could state a plausible claim for relief under the amended reverse false claim provision of the FCA for overpayments withheld after the amendment went into effect, because, if the government overpaid the clinic and the clinic intentionally refused to investigate that possibility, it may have unlawfully avoided an obligation to the government. *Id.* at *10. In this case, the court similarly did not apply the correct "knowing and improper" standard.

CONCLUSION

The stakes are high regarding an appropriate construction of the FCA's overpayment provision. Every large health care entity that submits claims to the government experiences a substantial volume of questions regarding claims submission from internal review, employees, governmental review from multiple organizations (MACs, RACs, etc.), compliance hotlines, and anonymous calls.

An issue that arises is this: If a health care claim is questioned in any fashion, what is a health care provider's duty to investigate or else be accused of committing fraud against the United States by violating the FCA, a statute providing for treble damages and substantial civil penalties and substantially enforced by private, financially self-interested, nonpolitically accountable *qui tam* relators? If the questioned claim is far-fetched or uncorroborated, or it appears unsupported, how much resources must a health care entity dedicate to the issue without being accused of violating the FCA? Moreover, how through must the review be? For example, if questioned claim is worth $1,000, but to conduct an appropriate medical review of the claim and a regulatory review to determine whether the underlying service was appropriately billed in light of the often conflicting guidance would cost the health care entity $5,000, must the entity spend $5,000 to learn whether there is a $1,000 overpayment or violate the FCA?[22] Finally, how much of their scarce resources should health care entities divert from patient care to track down, in detail, every unsupported or uncorroborated concern that an entity may have received an overpayment?

Luckily, for health care entities, the statutory language and legislative history indicate that where Congress drew the line was that the duty to investigate is triggered only when failure to conduct a review—based upon the facts and evidence presented to the entity—demonstrates that it would be inherently wrongful not to conduct a further review. Mere negligence, reckless disregard, or deliberate ignorance is insufficient. Instead, the information must be clear enough that the person will know that it is wrongful to retain the funds. Once this is understood, the FCA's overpayment provision will be kept within proper

[22] As one court noted, "Medicare regulations are among the most completely impenetrable texts within human experience." *See United States v. Medica-Rents*, 285 F. Supp. 2d 742, 770 (N.D. Tex. 2003) (internal quotation and citation omitted), *aff'd in relevant part*, 2008 U.S. App. LEXIS 17946 (5th Cir. Aug. 19, 2008). Frequently, with conflicting guidance in CMS Manuals, National Coverage Determinations, Local Coverage Determinations, Federal Register statements, statutory provisions and regulatory provisions, there is no simple answer to a coding issue.

bounds, and health care entities will not be compelled to hire an army of compliance staff to track down every concern or else be subject to suit under the FCA.