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Impending Qui Tams and False Claims Act Cases Involving Health Exchanges



By Kirk Ogrosky, Catherine A. Brandon, and John Kelly

I. *Health Insurance Exchanges*

Perhaps the critical apparatus for expanding coverage under the Patient Protection and Affordable Care Act (ACA)[1] is the creation of Health Insurance Exchanges (hereinafter ''Exchange'')—marketplaces where people can compare and purchase insurance coverage that meets minimum requirements.[2] Each state has two types of Exchange: (a) one for individuals and their families, and (b) one for small businesses and their employees. The latter exchange is known as the Small Business Health Options Program (SHOP).

States had several options for organizing and operating Exchanges. A state could establish and operate its own Exchange, work with other states to establish regional Exchanges, run an Exchange in partnership with the Federal government, or let the Department of Health and Human Services (HHS) operate a ''Federally-facilitated Exchange'' (FFE).[3]

Whether an exchange is run by a state, by the Federal government, or as a partnership between the two, the law mandates that Exchanges certify that the plans they offer are ''qualified health plans'' (QHP) that offer certain ''essential health benefits,'' meet specified cost-sharing requirements, and satisfy a litany of other requirements.[4]

Insurers wishing to obtain and maintain certification of their plan offerings are required to provide detailed information and data to the relevant Exchange. For instance, plan issuers must maintain ''transparency'' by making available to the public plan-level data regarding enrollment, claims, rating practices, as well as claims policies and practices.[5]

Further, to ''stabiliz[e] premiums in the individual and small group markets,'' the ACA establishes reinsurance, risk corridors, and risk adjustment programs,[6] which require QHP issuers to supply the Exchanges and HHS with detailed data. Much of this data is generated in the first instance by providers. HHS (and the

[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of the U.S. Code) (hereinafter ACA).

[2] ACA § 1311(b); 42 U.S.C. § 18031(b) (2010). Although the statute refers to these entities as ''Exchanges,'' more recently the Obama Administration has referred to them ''Marketplaces.''

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[3] ACA § 1321; 42 U.S.C. § 18041 (2010).

[4] ACA § 1301; 42 U.S.C. § 18021 (2010); ACA § 1311(e); 42 U.S.C. § 18031(e) (2010).

[5] ACA § 1311(e)(3); 42 U.S.C. § 18031(e)(3).

[6] ACA §§ 1341—1343; 42 U.S.C. §§ 18061—18063 (2010). Patient Protection and Affordable Care Act; Reinsurance, Risk Corridors and Risk Adjustment, 77 Fed. Reg. 17,220 (Mar. 23, 2012) (to be codified at 45 C.F.R. pt. 153). The first two programs are in effect for three years starting January 1, 2014. The third program is permanent.

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states) may provide payments to particular issuers based on the information provided to help cover the costs of certain high risk plans and high cost enrollees.

People with income between 100 and 400 percent of the Federal Poverty Level (FPL) may be eligible for Federal premium assistance subsidies, in the form of tax credits, to enroll in plans offered on an individual Exchange (as long as affordable employer-based coverage is not available).[7] These premium tax credits will be available to people immediately upon enrollment in a QHP, rather than after tax returns are filed. Advance payments of the tax credits go directly to insurers to pay a share of monthly premiums.

The Congressional Budget Office (CBO) projects that, of the 6 million people who will be covered by a QHP during 2014, about 5 million will receive tax credits to subsidize their premiums.[8]

Additionally, people with income between 100 and 250 percent of FPL may also be eligible for subsidies to help reduce cost- sharing if they enroll in certain Exchange plans.[9] Eligible individuals enrolled in a so-called ''silver'' plan (a plan which pays approximately 70 percent of covered medical services, with consumers responsible for 30 percent) will pay a reduced out-of-pocket cost-sharing directly to their providers. Insurers of individuals enrolled in ''silver'' plans will cover the difference, but will receive a subsidy payment each month from the Federal government based on estimates the insurers submit before the coverage year begins.

In short, the Federal government will be transferring billions of dollars a year to insurers to help pay premiums. The credits and subsidies are expected to total more than $1 trillion over 10 years.[10]

II. *The False Claims Act*

The False Claims Act (FCA) imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to the Federal government.[11] One acts ''knowingly'' when operating either with ''actual knowledge'' of the falsity of the claim or statement, or with ''reckless disregard'' for whether the claim or statement is true or false.[12] Proof of a specific intent to defraud is not required.[13] However, ''innocent mistakes or negligence are not actionable.''[14]

The government may bring suit under the FCA. Alternatively, a relator may also initiate a civil *qui tam* action on behalf of the government, and the government has the option of intervening as a party.[15] FCA liability carries a civil penalty of up to $10,000 per claim and triple ''the amount of damages which the Government sustains because of the act.''[16]

The government has recovered nearly $39 billion under the False Claims Act between 1987 (after the significant 1986 amendments) and 2013.[17] Of this amount, over $27 billion, or 70 percent, was from *qui tam* cases brought by relators.[18] In 2013 alone, DOJ secured $3.8 billion through the use of FCA actions, with $2.6 billion related to healthcare fraud.[19]

III. *FCA Applicability to QHPs and Providers in the Exchanges*

A. ACA's Explicit Extension of FCA to the Exchanges

The ACA extends FCA liability to ''payments made by, through, or in connection with an Exchange . . . if those payments include any Federal funds.''[20] Given that the vast majority of individuals purchasing insurance in an Exchange are expected to receive premium tax credits, this provision will likely apply to many payments made to both QHP issuers and healthcare providers offering services to QHP enrollees.

Further, Federal payments made pursuant to the reinsurance, risk corridors and risk adjustment programs could trigger FCA liability if insurance companies are found to have either purposely or recklessly submitted erroneous data, even though that information is not a formal claim for payment.

In *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp.2d 125 (E.D. Pa. 2012), the government submitted a Statement of Interest stating its belief that

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[7] ACA § 1401; 26 U.S.C. § 36(a) (2010).

[8] Congressional Budget Office, *Updated Estimates of the Effects of the Insurance Coverage Provisions of the Affordable Care Act* (April 2014), p. 10, Table 3, http://www.cbo.gov/sites/default/files/cbofiles/attachments/45231-ACA_Estimates.pdf.

[9] ACA § 1402; 42 U.S.C. § 18071 (2010).

[10] Robert Pear, *Strategic Move Exempts Health Law From Broader U.S. Statute*, New York Times (Nov. 4, 2013), http://www.nytimes.com/2013/11/05/us/politics/federal-health-law-may-not-be-a-federal-health-care-program.html?pagewanted=all&_r=0.

[11] 31 U.S.C. § 3729(a) (2009).

[12] *Id.* § 3729(b); *see, e.g.*, *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1224 n. 11 (11th Cir. 2012); *United States ex rel. A+ HomeCare, Inc. v. Medshares Mgmt. Grp., Inc.*, 400 F.3d 428, 451 (6th Cir. 2004).

[13] 31 U.S.C. § 3729(b)(1)(B). As one court has instructed a jury in the Stark context, ''[i]t is not necessary that the United States prove that the defendant intended to submit false claims. . . . In order to find that [defendant] took action knowingly, you . . . would need to find that at least one individual employee or agent of [defendant] knew that [defendant] was submitting claims to Medicare and knew that the claims were false.'' *United States ex rel. Drakeford v. Toumey Healthcare Sys., Inc.*, 675 F.3d 394, 401 (4th Cir. 2012).

[14] *United States ex rel. Parato v. Unadilla Health Care Ctr., Inc.*, 787 F. Supp. 2d 1329, 1339 (M.D. Ga. 2011) (citing *Hindo v. Univ. of Health Scis.*, 65 F.3d 608, 613 (7th Cir. 1995)); *accord United States ex rel. Kosenske v. Carlisle HMA, Inc.*, No. 1:05-CV-2184, 2010 WL 1390661, at *7 (M.D. Pa. Mar. 31, 2010) (''[N]egligent or innocent mistakes are not actionable'' (citing *Hindo*)); *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 232 (5th Cir. 2008) (finding that evidence of provider's erroneous billing did not support an inference of scienter since the billing included both over-billing *and* under-billing errors).

[15] *See* 31 U.S.C. § 3730(b)(1). ''*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means 'who pursues this action on our Lord the King's behalf as well as his own.' '' *Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 768 n.1 (2000).

[16] 31 U.S.C. § 3729(a)(1)(G); 28 C.F.R. § 85.3(a)(9) (2014) (adjusting for inflation).

[17] *Fraud Statistics—Overview, Oct. 1, 1987 – Sept. 30, 2013* U.S. Dep't of Justice (Dec. 23, 2013), http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

[18] *Id.*

[19] *Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013*, U.S. Dep't of Justice (Dec. 20, 2013), http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html.

[20] ACA § 1313(a)(6); 42 U.S.C. § 18033(a)(6) (2010).

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plan prescription drug event (PDE) submissions to CMS are ''claims'' under the FCA. The court agreed with the relator that submission of PDE data caused the government to make payments under Part D.[21] The government or a *qui tam* relator could employ similar theories in cases related to Exchanges.

The vulnerability that issuers (and the providers that supply them information) face is not mere speculation. The government has stated its intent to use the FCA with these programs. For instance, states are required ''to maintain all records related to the reinsurance program for 10 years consistent with requirements for record retention under the FCA.''[22] Records related to risk adjustment also must be retained for 10 years.[23]

Further, HHS affirmed its intent to rely on FCA enforcement with regard to validating risk adjustment data:

> [W]e continue to believe that in light of the complexity of the data validation process, two years of observation experience will help HHS refine its data validation process by enabling us to gather sufficient data on issuer and auditor error, and will provide issuers and auditors enough time to adjust to the audit program. Although we are not adjusting payments and charges based on error rates, we note that other remedies, such as prosecution under the False Claims Act, may be applicable to issuers not in compliance with the risk adjustment program requirements when HHS operates risk adjustment on behalf of a State.[24]

Whistleblowers and DOJ already have used the FCA against Medicare Advantage plans and providers based on similar theories.[25]

Moreover, Congress made sure that FCA liability in the Exchanges would include liability under a ''false certification'' theory, which finds claims to be false ''when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.''[26]

In the context of Medicare, the success of a false certification claim depends on whether it is based on ''conditions of participation'' in the program (which do not support an FCA claim) or on ''conditions of payment'' from Medicare funds (which do support FCA claims).[27]

The ACA eliminates this distinction by providing ''[c]ompliance with the requirements of [the ACA] concerning eligibility for a health insurance issuer to participate in the Exchange shall be a material condition of an issuer's entitlement to receive payments, including payments of premium tax credits and cost-sharing reductions, through the Exchanges.''[28]

Thus, any attestations or commitments that insurers make as part of the QHP application process could become a basis for liability under the FCA should any of those statements be found to be false. Liability also could arise under an ''implied certification'' theory if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned.[29]

Between the application process and the continued data submission requirements under the transparency, reinsurance, risk corridors, and risk adjustment program requirements, there are potentially significant opportunities for the government or a relator to allege that some erroneous data is the basis of FCA liability.[30]

B. Restriction of Jurisdictional Bar to *Qui Tam* Suits

The ACA also restricted the jurisdictional limits on *qui tam* suits by narrowing the ''public disclosure'' bar and broadening the definition of ''original source,'' making it easier for relators to bring FCA suits, including in the context of the Exchanges. Traditionally, the bar prohibited *qui tam* suits based on information that previously had been disclosed to the public, unless the whistleblower qualified as an ''original source'' of the information.

First, ACA narrowed the types of information that could trigger the public disclosure bar. Before ACA, the public disclosure bar was broader, applying to public disclosures at the Federal, state, and local level. ACA removed the ability to bar a *qui tam* when that information was provided on the state or local level; instead, a

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[21] The Statement of Interest may be found at https://docs.google.com/file/d/0B9k5Ar6oRsYWcDV3V3lLY0JTMnc/edit?pli=1.

[22] Patient Protection and Affordable Care Act; Reinsurance, Risk Corridors and Risk Adjustment, 77 Fed. Reg. at 17,229. This requirement may be found at 45 C.F.R. § 153.240(c) (2013).

[23] 45 C.F.R. § 153.620(b) (2014).

[24] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014, 78 Fed. Reg. 15,410, 15,438 (Mar. 11, 2013) (to be codified at 45 C.F.R. pts. 153, 155, 156, 157, and 158). QHPs are subject to risk adjustment data validation (RADV), which requires two levels of audits—first an audit by an independent third party paid for and selected by the plan issuer, and a second government audit by HHS. For both levels, HHS selects the sample to be audited, and plans are not permitted to supplement documentation after the initial audit. 45 C.F.R. § 153.630 (2014).

[25] *See United States v. Janke*, No. 09-14044-CIV, 2009 WL 2525073 (S. D. Fla. Aug. 17, 2009); *UnitedStates ex rel. Swoben v. SCAN Health Plan*, No.CV09-5013JFW(JEMx) (Cent. Cal. Nov. 23, 2011).

[26] *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011).

[27] *United States ex rel. Hobbs v. Medquest Assocs.*, 711 F.3d 707, 714 (6th Cir. 2013).

[28] ACA § 1313(a)(6); 42 U.S.C. § 18033(a)(6).

[29] *See, e.g., Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467-68 (6th Cir. 2011).

[30] The government or a relator could allege provider liability under a false certification theory, as well. Providers participating in QHPs enter into provider agreements with issuers, which require them to certify the accuracy of their claims and general compliance with laws. Misrepresentations to QHPs or noncompliance with their provider agreements could be the basis of FCA liability. *See Wilkins*, 659 F.3d at 307 (holding that FCA liability may exist even though the complaint does not identify a particular false claim, as long as the defendant submitted a claim for payment while in knowing noncompliance with a statute or regulation to which it had certified compliance); *United States v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp.2d 430, 438 (E.D. Pa. 2004) (''Plaintiffs have sufficiently alleged numerous false or fraudulent statements by Medco. Specifically, the Government has alleged that Medco submitted annual certifications to Blue Cross that were untrue and that Medco submitted claims for payment for services that were not rendered or *that were not performed in accordance with contractual requirements*. . . . Medco argues that, even if Plaintiffs' allegations are true, their allegations would not rise to the level of actionable fraud. The Court disagrees. The FCA reaches all fraudulent attempts to cause the Government to pay out sums of money.'') (internal quotations and citations omitted) (emphasis added).

whistleblower suit cannot be barred unless ''substantially the same allegations or transactions were publicly disclosed'' in: (1) ''a Federal criminal, civil, or administrative hearing in which the government or its agent was a party;'' (2) ''a congressional, [GAO], or other Federal report, hearing, audit, or investigation,'' or (3) ''from the news media.''[31]

Thus, arguably, data and other information freely provided by insurers to, at the very least, state-run Exchanges pursuant to their various certification, transparency, and reporting requirements could be used by relators as the basis to bring suit.[32]

ACA also broadened the definition of ''original source.'' Previously, an original source needed ''direct and independent knowledge of the information on which the allegations were based,'' and must have voluntarily provided that information to the government before filing an FCA suit based on that information.

ACA expanded the definition of ''original source'' to also include any individual who has knowledge that is ''independent of and *materially adds* to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing [the suit].''[33]

Thus, even if data and information provided to the Exchanges has been publicly disclosed, relators could still bring suit if they allege knowledge that materially adds to the publicly disclosed information.

ACA's extension of the FCA to the Exchanges, together with the statute's amendments to the FCA weakening prior jurisdictional bars, as well as the sheer amount of money at issue, make the Exchanges a potentially fertile ground for relators.

IV. *Uncertainty Regarding Cases Based on AKS Violations in Exchanges*

The applicability of the Anti-Kickback Statute (AKS), and derivative FCA liability, in Exchanges remains uncertain due to a series of strange and poorly communicated steps by HHS and CMS.

The AKS prohibits any person from knowingly or willfully paying remuneration (e.g., a thing of value) to any person with the intent to induce the person to purchase, prescribe, recommend, or refer a person for the furnishing of items and services *payable under a Federal health care program*.[34] The ACA amended the AKS to provide that ''a claim that includes items or services resulting from'' an AKS violation is, *per se*, a ''false or fraudulent claim'' under the FCA.[35]

Thus, a false claim can be established under the FCA merely by proving that a defendant billed Medicare or Medicaid for treating a patient whose referral was unlawfully induced via kickback. However, ACA is not retroactive,[36] so this *per se* rule of falsity only applies to claims for payment filed after ACA's enactment.

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After passage of the ACA, there was significant speculation and debate as to whether QHPs or other aspects of the Exchanges would be considered Federal healthcare programs for purposes of the AKS, given that several features involve Federal funding.

In an Oct. 20, 2013, letter to Rep. Jim McDermott (D-Wash.), HHS Secretary Kathleen Sebelius stated:

> The Department of Health and Human Services does not consider QHPs, other programs related to the federally-Facilitated Marketplace, and other programs under Title I of the Affordable Care Act to be federal healthcare programs. This includes the State-based and Federally-facilitated Marketplaces; the cost-sharing reductions and advance payment of the premium tax credits; Navigators for the Federally-facilitated Marketplaces and other federally funded consumer assistance programs; consumer-oriented and operated health plan; and the risk adjustment, reinsurance, and risk corridor programs.[37]

While the HHS statement seems clear, and it is hard to imagine how a court could look at any FCA case seriously after the Secretary opined so concisely, some relators' counsel and DOJ personnel have hinted that courts are not bound by HHS positions. Indeed, the Supreme Court has said that ''[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron-style* deference. They are 'entitled to respect,' but only to the extent that they are persuasive.''[38] The fact that HHS does not enforce criminal law may also undermine the persuasiveness of Sebelius' position.

Moreover, only two weeks after Sebelius' letter, CMS released an FAQ that discouraged providers and com-

[31] 31 U.S.C. § 3730(e)(4)(A) (2010). Ironically, on March 30, 2010, one week after President Obama signed PPACA, the Supreme Court decided that whistleblower allegations based on publicly disclosed information in state or local reports are barred. The Court acknowledged the PPACA's change but ruled that the amendment would not be retroactive, and stated that the decision applied to the pre-PPACA FCA. *Graham Cnty. Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 n. 1 (2010).

[32] Arguably, Federally-facilitated Exchanges would be considered an arm of the Federal government, such that publicly reported data from those Exchanges would bar a *qui tam* action on the basis of substantially similar information; however, this point has yet to be litigated.

[33] 31 U.S.C. § 3730(e)(4)(B) (2010) (emphasis added).

[34] *See* 42 U.S.C. § 1320a-7b(b) (2010).

[35] *Id.* at § 1320a-7b(g).

[36] *See Graham Cnty. Soil & Water Conserv. Dist.*, 559 U.S. at 283 n.1.

[37] Letter from Kathleen Sebelius, Secretary, HHS, to Rep. Jim McDermott, U.S. House of Representatives (Oct. 30, 2013), *available at* http://www.hpm.com/pdf/blog/The-Honorable-Jim-McDermott.pdf.

[38] *Christensen v. Harris Cnty.*, 529 U.S. 576, 577 (2000) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

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mercial entities from providing premium and cost-sharing assistance to individuals enrolled in QHPs, and encouraged issuers to reject such third party payments. While CMS suggested that the basis for their concern was that these payments could ''skew the insurance risk pool and create an unlevel field,'' rather than AKS risks, this statement has created significant confusion in the market and has called into question whether Sebelius' letter could be relied upon.[39]

Thus, even if future administrations respect HHS's current position and decline to pursue would-be AKS violations in the Exchanges, relators may bring FCA cases based on AKS theories in hopes they can convince courts that HHS's position was not persuasive and, ultimately, incorrect.

V. *Avoiding Qui Tams and False Claims Act Liability*

Given all of these factors, QHP issuers, as well as healthcare providers offering services to individuals enrolled in QHP plans, need to develop strong compliance protocols regarding claims and data submission. Compliance and internal controls can both improve data accuracy and mitigate against accusation that erroneous data was submitted with reckless disregard of truth or falsity.[40]

The development and execution of compliance plan protocols centered around data collection and submission should take into account computer systems, data exchange, accounting and actuarial calculations, as well as the way data and payments flow among the Exchanges, HHS, providers, and insurers.

QHP issuers will need to provide HHS with information regarding individuals eligible for advanced payments of the premium tax credit, as well as cost-sharing reductions, on a monthly basis. QHP issuers should reconcile payments received to account for errors and data discrepancies, as well as actual costs incurred.[41]

Timely and accurate reconciliation will be important because, if an insurer receives overpayments of which it either knows or should have known, retaining that overpayment could be the basis of liability under a reverse FCA theory.[42]

As discussed above, issuers must also submit enrollee-level data to either HHS or a state in order to calculate risk adjustment payments and charges, as well as reinsurance payments. Much of the data provided to HHS is generated by providers, putting issuers in the position of having to collect, as well as monitor the quality of, the data generated by a large number of providers.

In anticipation of upcoming suits and government inquiries, wise legal counsel should encourage and require compliance program protocols that include a focus on the following elements:

Data Collection, Retention and Submission:

A key element in any compliance program must be data integrity. Both providers and issuers should establish procedures and employ health IT systems that ensure that data collection, retention, and submission (either to issuers or the government) is done in a way that preserves the accuracy of the data. For instance, the existence of duplicate patient records or lack of controls over who may enter or edit information, could undermine data accuracy and put both providers and issuers at risk.[43]

Accounting & Actuarial Assumption Integrity:

Many of the ACA's provisions increase the need for actuary estimates in health insurance issuers' financial reporting and create accounting uncertainty. The premium stabilization programs, new taxes and fees, advanced payments to issuers, and other market reforms will need to be addressed in the actuarial estimates found on issuers' balance sheets and other accounting policy decisions.[44] In addition to having implications in securities and corporate law, these decisions may have implications regarding an issuer's compliance with medical loss ratio (MLR) requirements. Plans that improperly avoid an obligation to make MLR rebate payments arguably could face FCA liability as well.

Thus, it is important that issuers' accounting and actuarial practices are consistent with Generally Accepted Accounting Principles and other best practices. Compliance programs should ensure that any accounting or actuarial assumptions made are clearly documented and explained.

Education:

Given the novelty of the Exchanges, issuers should offer and encourage their employees and contracted providers to participate in educational sessions regarding the new premium stabilization programs and the

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[39] *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces FAQ*, CMS (Nov. 4, 2013), *available at* http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf. CMS reiterated this position in an interim final rule requiring QHP issuers to accept government-sponsored payment assistance. Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums, 79 Fed. Reg. 15,240, 15,242 (Mar. 19, 2014) (to be codified at 45 C.F.R. pt. 156).

[40] *See, e.g.*, *Kosenske*, 2010 WL 1390661, at *9 (denying cross-motions for summary judgment on AKS-related FCA claim because of genuine factual issues as to corporate knowledge, where defendants' evidence ''suggest[ed] a careful compliance investigation that determined the hospital was acting in accordance with the [applicable law]'' and one compliance officer concluded that ''the terms of the arrangement [at issue] were consistent with industry standards,'' and explaining that ''[e]ven if the conclusions of the hospital audits were legally erroneous, there is sufficient evidence [for a reasonable jury to find] that they were undertaken in good faith by competent officers''); *Merck-Medco Managed Care*, 336 F. Supp. 2d at 440-41 (holding that government adequately pled ''reckless disregard'' by alleging that defendant's ''compliance programs were either non-existent or insufficient'').

[41] HHS has issued an enrollment guide with technical specifications for the data flows from Federally-facilitated Exchanges and issuers to HHS, including monthly reconciliation of enrollment data, and HHS has asked the state-based Exchanges to use the same guidance when sending enrollment files to CMS or to issuers. *Standard Companion Guide Transaction Information*, CMS (Mar. 22, 2013), *available at* http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/companion-guide-for-ffe-enrollment-transaction-v15.pdf.

[42] 31 U.S.C. § 3729(a)(G).

[43] Additionally, compliance measures should promote health data stewardship, consistent with privacy rules.

[44] For a more extensive discussion regarding these issues, see Health Practice Financial Reporting Committee, American Academy of Actuaries, *Financial Reporting Implications Under the Affordable Care Act* (June 2013), *available at* http://www.actuary.org/files/HPFRC_White_Paper_on_ACA_and_FR_final_062513.pdf.

importance of medical record documentation and claims accuracy. Such sessions are important not only in the context of Exchanges, but also as the information relates to payment in general, since inappropriately reimbursed claims could be grounds for FCA liability if the enrollee receives Federal assistance. These educational programs should include information about how the data submission systems will operate and what information will need to be provided.

Provider Contracting:

Risk adjustment regulations allow issuers to enter into contractual arrangements with providers, suppliers, physicians, and other practitioners to ensure that issuers receive the data necessary for QHP issuers' submission of risk adjustment data.[45] Contractual mechanisms, such as bonuses for low error rates, can help ensure that providers are maintaining accurate and complete medical records and that insurers are receiving high quality data. Any financial incentives should be tied to the accuracy of the claims data, so as not to inadvertently incentivize upcoding.

Quality Assurance and Audit Programs:

Health plans and providers should have effective internal quality assurance and audit policies and procedures, above and beyond auditing required by HHS,[46] that include monitoring, data analytics, personal review of select claims and diagnosis, and internal audit plans. Insurers and providers need to ensure that companies providing audit and coding review services are qualified to provide the required services and are properly equipped to conduct those services in an unbiased manner.

VI. *Conclusion*

Simply understanding the data collection, storage, usage, and submission processes can be an enormous head start in terms of assuring compliance and positioning plans to address both government inquiries and potential FCA cases alleging reckless disregard theories of liability.

It goes without saying that an ounce of prevention is truly worth a pound of cure when it comes to FCA allegations and the potential of extortionist demands from individuals who are unwilling to understand the facts.

[45] 45 C.F.R. § 153.610(b) (2013).

[46] *See supra* note 24.

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