CORPORATE GRIEF: THE SIX STAGES OF COPING WITH A REPORTED COMPLIANCE PROBLEM

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When a company first learns of a reported compliance problem, the reaction of management will likely fluctuate from disbelief, to swearing they were given approval from regulators, to blaming their counsel. Much like the grieving process, the organization and its staff will work through multiple stages of emotions that not only impact how the company addresses the problem, but may also impact how government enforcers eventually deal with the company.

These stages parallel the stages of grief and may include: denial, disavowal, disclaimer, deflection, blame, and bargaining.

Stage 1. Denial: We Didn't Do That

An initial natural reaction to a potential compliance issue is to deny the reality of the situation. But ignoring a complaint will not only **not** make it go away, but could potentially provide fodder for an allegation the company is acting with "deliberate ignorance" or "reckless disregard" under the federal or a state false claims act. Indeed, the very essence of "deliberate ignorance" is said to be the "ostrich with his head in the sand," refusing to acknowledge what is in front of him, or put another way, refusing to learn of information which an individual, in the exercise of prudent judgment, had reason to know.[2]

Further, if the compliance concern is raised early enough, before conduct is undertaken or a new policy or procedure is implemented, the company can take steps to explore and understand the concern. A company that makes some effort to determine the legality of its actions may be creating a potential defense to any future *qui tam* for lack of scienter.[3]

But ignoring a compliance concern creates risk for the company.[4] Corporate indifference to reported compliance concerns may increase the chance someone with knowledge files a *qui tam* in the future; that indifference may also be used as evidence to establish the requisite level knowledge/scienter for a false claims action. Corporate indifference to reported compliance concerns may also increase the odds of eventual government intervention in a *qui tam.*

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[2] 31 U.S.C. § 3729(b)(1); S. Rep. No. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286.

[3] *See* United States *ex rel.* Williams v. Renal Care Group, Inc., 696 F. 3d 518 (6th Cir. 2012).

[4] *See* United States *ex rel.* Keltner v. Lakeshore Med. Clinic, Ltd., 2013 U.S. Dist. LEXIS 44640 at *9-10, 2013 (E.D. Wis. Mar. 28, 2013) (facing a "reverse" FCA claim allegation due to Clinic's decision to ignore rather than correct billing issue); *see also* Dept. of Health and Human Serv. Office of the Inspector General, Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security (*available at* http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf).

And the risk is not just to the company. In the present enforcement environment, the government may be focused on individual as well as corporate liability, so ignoring a compliance risk can expose individuals with an ownership or management interest to liability or possible exclusion.[5]

State 2. Disavowal: We Didn't Understand The Rules/Rules Are Vague.

After recovering from the initial desire to outright deny the problematic practice even occurred, organizations may enter the disavowal stage and blame vague rules or policies.

The idea that regulations are vague or ambiguous is not without merit. In *U.S. ex rel. Williams v. Renal Care Group*, the court found that the defendant did not act with the necessary scienter to violate the federal false claims act because it sought clarification from counsel and the Centers for Medicare & Medicaid Services (CMS) on what was required under the purportedly vague regulatory provisions. But it was the fact the company took documented action to try and clarify what was required under those provisions that won the day – if the company was trying to determine what was necessary under the law, it could not be said to be acting with reckless disregard or deliberate ignorance of the law.[6]

Organizations may also want to explore whether the governing legal provisions involve conditions of payment, versus conditions of participation. In some circuits, it is a potential defense to a false claims action that the provisions violated did not implicate a condition of payment.[7] As the Tenth Circuit explained: "Conditions of participation . . . are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program. . . .while [c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment."[8] Recent cases in which the court determined that a violation impacted a condition of participation, as opposed to a condition of payment include ones involving compliance with Medicare Advantage marketing guidelines,[9] use of non-supervising physicians to oversee contrast testing, [10] billing under a previous owner's National Provider Identifier (NPI),[11] and violations of the Clinical Laboratory Improvement Amendments (CLIA).[12]

The problem with the conditions of participation v. payment argument is that a company may have to wait until a *qui tam* is brought, and litigated, before succeeding on the issue. So while it is worth exploring, a company may not want to rest its entire compliance review on whether or not it needs to comply with a particular provision because it is not a condition of payment.

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5 Dept. of Health and Human Serv. Office of the Inspector General, Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security (*available at* http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf).

6 Renal Care Group, Inc., 696 F. 3d 518 at 531.

7 United States *ex rel.* Wilkins v. United Health Group, Inc., 659 F. 3d 295, 309-310 (3d Cir. 2011).

8 United States *ex rel.* Conner v. Salina Regional Health Center, 543 F. 3d 1211, 1220 (10th Cir. 2008).

9 *See* United Health Group, Inc., 659 F. 3d at 309-310 (3d Cir. 2011).

10 *See* United States *ex rel.* Hobbs v. MedQuest Associates, Inc., 711 F. 3d 707 (6th Cir. 2013).

11 *See* Id.

12 *See* United States *ex rel.* Hansen v. Deming Hospital Corporation, No. CV 11-566 WPL/CG (N.M.D.C 2013).

Stage 3. Disclaimer: CMS/Medicare/Medicaid/Contractor Told Us This Was OK

After denial and disavowal, organizations may try to establish that the agencies at issue provided guidance or statements that led to a reasonable belief that the conduct at issue was permissible. If the company sought advice from a government entity, or its designated contractor, it was not acting with reckless disregard or deliberate ignorance in the propriety of its conduct.

But as a practical matter, the burden will be on the company to establish that it contacted and received advice from a government agency or it designated contractors. If the company merely asserts that "Medicare said it was ok" the response will either be that the building does not talk, or "prove it." Indeed, in a 2012 Sixth Circuit case involving the *Renal Care Group,* the government repeatedly denied the company sought CMS clarification on regulations, despite the company's insistence otherwise, until well into the litigation when the government found "inadvertently" archived documentation of the contact.[13]

We recommend health care organizations adopt and implement policies mandating its employees document initiating and completing contact with any government employee or representative, including the date, email/telephone number contacted, name and title of person contacted/ responding, nature of inquiry, summary of advice given, and any other pertinent information. If the contact is initiated and received by telephone, the protocol should require the employee to send a confirmation email or letter.

Stage 4. Deflection: Everyone Else Is Doing It

Although it is easy and natural to find comfort in the fact that your organization is not the only one utilizing a particular practice, this comfort does not equal an affirmative defense. Universally, don't all mothers say "if everyone else jumps off the bridge, will you?" The argument that everyone else's mother was letting them stay out all night at an unchaperoned party did not work with your mother, and it is not going to work with the government. The response will be: tell us who the "everyone else" is, and we will deal with them after you.

When a health care company has a sales/marketing function, the business pressures on this point can be intense. Legal and compliance staff will be lobbied to approve practices based on an argument that everyone else is doing it, so failure to adopt this practice will be devastating to the company's bottom line. However, every drug maker that manufactured an atypical anti-psychotic drug ended up facing false claims and off-label marketing violations. Teaching hospitals that faced enforcement actions over physician billing for resident services did not get reprieves because other hospitals billed in the same manner. Companies, and their compliance and legal professionals, need to recognize that the "everybody else's mother defense" is no defense.

[13] Renal Care Group, Inc., 696 F. 3d at 524 (6th Cir. 2012).

Stage 5. Blame: Blame X, It Was His Fault, But Not Ours

After organizations try to blame the regulations or the regulators, they may turn on someone internal: a member of the compliance or legal team, a contractor, or a consultant, who they assert approved the practice.

It is true that good faith reliance on the advice of counsel, or a knowledgeable consultant, may negate the scienter required to commit a false claims violation.[14] But the opinion is only as good as the factors provided: withholding relevant or salient facts may negate the "good" in good faith. Areas of inquiry should include:

- Whether the person giving the opinion was provided all pertinent facts;
- Whether the person asking for the opinion had already requested or received other opinions, and if he/she shared those opinions as part of any subsequent inquiries;
- Whether the person asking for the opinion sought it from the person in the organization or affiliated with the organization who was best qualified to render a competent opinion;
- Whether the person giving the opinion was diligent in researching the issue;
- Whether the person giving the opinion was right on the law; and,
- Whether the person asking for the opinion followed all aspects of the opinion response or cherry-picked the portions followed.

Health care entities also need to understand that the ability to negate scienter under the false claims act does not excuse the entity from all responsibility. Under applicable regulations or provider agreements, a health care entity will be responsible for the truth or accuracy of its claims submissions and billings and the practices underlying those claims/billings, regardless of the involvement of a third party vendor or contractor. There still may be a responsibility to redress claims submission/payments as a result of the practice at issue.

Stage 6. Bargaining/Acceptance: Can't We Just Change Our Practices Going Forward; We Don't Need to Report This To Anyone, Do We?

After going through the previous phases and finding no viable defenses to a problematic compliance issue, most companies are tempted to look forward, not backwards, and want to limit redress to future practices. That may be the riskiest proposition of all.

Today, the vast majority of government enforcement is driven by *qui tams*, with the U.S. Justice Department reporting that 753 of its 846 new fraud cases for the first 9 months of 2013 stemmed from *qui tam* filings.[15]

As most health care practitioners know, *qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means "[he] who sues in this matter for the

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[14] *See e.g.,* United States v. Newport News Shipbuilding, 276 F.Supp.2d 539 (E.D. Va. 2003) (applies to FCA); United States *ex rel.* Pogue v. Diabetes Treatment Centers of America, 565 F.Supp.2d 153 (D.D.C. 2008).

[15] *See* Dept. of Justice, Civil Division, Fraud Statistics Overview p. 2, (Dec. 2013) *available at* http://www.justice.gov/sites/default/files/civil/legacy/2013/12/26/C-FRAUDS_FCA_Statistics.pdf.

King as well as for himself."[16] The theory underlying a *qui tam* is that someone with inside information of the fraud is bringing forth information about it to the government by filing suit in the name of the government. This is why the federal false claims acts, and the overwhelming majority of state false claims acts, require that a *qui tam* relator be the original source of information about the fraud.

If a company fully discloses non-compliant action to the government, the disclosure does not eliminate the chance of a *qui tam*. But it does mitigate the chance of a successful *qui tam*: if the government already knows the relevant facts, the relator cannot truly be said to be the source of its information.

There are several options for disclosure of non-compliant conduct, including the OIG Voluntary Disclosure Protocol, the CMS Voluntary Self-Referral Disclosure Protocol Disclosure for Stark violations, or just meeting with a U.S. Attorney. But disclosure must be an all or nothing proposition: including the bad with the good. Failing to diligently explore and report all areas of non-compliant conduct is as risky as ignoring the compliance concern altogether.

In *United States ex rel. Keltner v. Lakeshore Medical Clinic*,[17] the clinic discovered upcoding errors during internal audit based on sampling and did in fact correct the specific claims identified in the sample. But according to the relator, the audit showed that two physicians were consistent coding outliers, which should have led to a broader examination and correction of their claims. Not only did the clinic management refuse to examine other claims, it elected to cease future audits, leading to a *qui tam* filing.[18]

Recommendations

How a health care company addresses and redresses a reported compliance concern not only impacts the chance of a future *qui tam* filing based on the conduct, it also impacts how the government may view that *qui tam* for intervention purposes. *Qui tam* mitigation can occur in the early stages, as the organization processes through its denial, disavowal, deflection, blame and bargaining stages.

So here are some recommended steps to consider:

1. Ensure your organization is committed to fostering a "culture of compliance", through which it welcomes reports of compliance concerns or questions, and provides positive reinforcement to those who report such concerns or questions.

2. Ensure Human Resource policies reflect that all employees, managers, trusted advisors, and contractors are expected to report any compliance concerns; the policies should also

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[16] *See* United States *ex rel.* Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 509 n. 1 (3d Cir. 2007) (quoting Vt. Agency of Natural Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 769 n. 1 (2000)).

[17] 2013 U.S. Dist. LEXIS 44640, 2013 (E.D. Wis. Mar. 28, 2013).

[18] Id. at 9.

mandate that managers appropriately address compliance concerns or face discipline for failure to do so.

3. Treat those who report concerns with respect and attentiveness, and ensure policies protect those individuals from retaliation.

4. Require that all compliance concerns and complaints be investigated.

5. Ensure that the loop is closed: Relay a summary of findings to those that reported and reinforce your appreciation for the report. If the report was anonymous, consider briefly describing the reported concern and resulting action in a company newsletter or on the intranet, with an expression of appreciation for the anonymous reporting. Nothing increases the possibility of an insider *qui tam* than someone who reported the compliance concern to the company and, due to lack of feedback, believes his or her report was ignored.

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