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# Are We Bulletproof?: A Defensive Business Strategy to Protect Health Care Companies from False Claims Act Litigation and Corporate Integrity Agreements

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## ARTICLE

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### ARE WE BULLETPROOF?: A DEFENSIVE BUSINESS STRATEGY TO PROTECT HEALTH CARE COMPANIES FROM FALSE CLAIMS ACT LITIGATION AND CORPORATE INTEGRITY AGREEMENTS

By: Jim Moye\*

*"The days of scamming dollars from our health care system are over. Thanks to new tools contained in the Affordable Care Act, we are more prepared than ever to safeguard taxpayer dollars and ensure that the health care coverage of our seniors, families and children is secure."*<sup>[1]</sup>

Health care fraud has become a hot topic in corporate America. In Fiscal Year 2007, an estimated \$2.26 trillion was spent on health care in this country.<sup>2</sup> All governments, but especially the United States government, stepped up efforts to combat fraud, abuse, and waste in the health care system. In 2009 alone, the Department of Justice, in conjunction with other federal agencies, filed 800 indictments, obtained over 600 convictions, and recouped over \$3 billion in health care fraud cases prosecuted through the False Claims Act.<sup>3</sup> The Federal Bureau of Investigations claimed it investigated over 2,400 cases of health care

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<sup>1</sup> See HHS Secretary Sebelius, *U.S. Attorney General Holder Kick Off First Regional Health Care Fraud Prevention Summit in Miami, Florida*, DRUG WK., Aug. 6, 2010, at 247, 2010 WLNR 15084270 at 247 (2010).

<sup>2</sup> See Beth Fitzgerald, *Insurer Sniffs Out Fraud Amid Soaring Health Care Costs*, N.J. BIZ, Sept. 6, 2010, at 5, available at 2010 WLNR 19029436.

<sup>3</sup> Press Release, U.S. Dep't of Justice, Attorney Gen. Eric Holder speaks at the 2010 Bench/Bar Conference in PA, (Sept. 17, 2010) available at <http://www.justice.gov>. ("In addition, through a new partnership with the Department of Health and Human Services, we've brought the full resources of the federal government to bear against those who illegally divert taxpayer resources from government-funded healthcare programs. Last year, the Department filed more than 800 indictments, and obtained nearly 600 convictions, for health care fraud-related charges. And, over the past 20 months, the Department has recouped close to \$3 billion in health care fraud cases through use of the False Claims Act.")

fraud in one year.<sup>4</sup> In July 2010, the Department of Justice announced arguably the largest health care fraud sting in history when it brought charges against 94 people, located in five different states.<sup>5</sup> The government charged that the case involved \$251 million in Medicare payments for services that were either medically unnecessary or never performed.<sup>6</sup> One piece of the case, worth an alleged \$70 million, took place in New York and alleged over 1,000 cash “kickbacks” were paid to Medicare beneficiaries.<sup>7</sup> The case implicated doctors, health care company owners, and executives.<sup>8</sup>

Another noteworthy case involved AstraZeneca. The pharmaceutical giant allegedly illegally marketed an anti-psychosis medication for uses not deemed safe and effective, also known as “off-labeling.”<sup>9</sup> The settlement agreement signed by the company alleged that marketing the drug for unapproved purposes caused payment for false claims to Medicare, Medicaid, TRICARE programs, the Department of Veterans Affairs, the Federal Employee Health Benefits program, and the Bureau of Prisons.<sup>10</sup> For its perceived transgression, AstraZeneca paid a civil fine of \$520 million and agreed to a second, five-year Corporate Integrity Agreement with the Department of Health and Human Services.<sup>11</sup> Finally, there were lesser allegations that AstraZeneca violated Anti-Kickback Statutes by making illegal payments to doctors to serve as authors for studies already completed by AstraZeneca, paying for doctors to lecture on the unapproved uses of the drug and paying doctors to travel

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<sup>4</sup> Carrie Johnson, *53 in Detroit and Miami Indicted in Medicare Fraud Sting*, WASH. POST, June 25, 2009, at A03.

<sup>5</sup> See Jerry Markon, *94 Caught in Major Health-Care Fraud Sting*, SEATTLE TIMES, July 17, 2010, 2010 WLNR 14425674 at A6.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Pharmaceutical Giant AstraZeneca to Pay \$520 million for Off-Label Drug Marketing for Regulatory Agencies*, BIOTECH WK., May 12, 2010, 2010 WLNR 9382973 at 2506. Specifically, AstraZeneca allegedly marketed Seroquel for unapproved uses. See *id.* “Under the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for off-label uses.” *Id.* The allegations also included “between January 2001 through December 2006, AstraZeneca promoted Seroquel to psychiatrists and other physicians for certain uses that were not approved by the FDA as safe and effective (including aggression, Alzheimer’s disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness).” *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> See *id.* As part of the \$520 million settlement the federal government received \$301,907,007 from the civil settlement, state Medicaid programs and the District of Columbia will share up to \$218,092,993 of the civil settlement. See *id.* Additionally, AstraZeneca was already under a Corporate Integrity Agreement with the Department of Health and Human Services. See *id.*

to resorts to “advise” AstraZeneca managers on unapproved uses of the drug.<sup>12</sup>

Maryland was rocked by one of the more gruesome tales of health care fraud. Dr. Mark Midei, considered one of the top cardiologists in Maryland, served as the Cardiology Department Chairman for the St. Joseph Medical Center in Towson, Maryland.<sup>13</sup> Dr. Midei joined the hospital in January 2008 and conducted a number of heart stent procedures on patients.<sup>14</sup> In fact, between January 2008 and January 2010, when he was relieved of his duties with the hospital, Dr. Midei performed at least 2,000 separate procedures.<sup>15</sup> In late 2009, the hospital received a complaint from one of Dr. Midei’s patients, who also was a hospital employee.<sup>16</sup> The complaint forced the hospital to review a sample of Dr. Midei’s cases and what they discovered was astounding.<sup>17</sup> After reviewing just under 2,000 of the doctor’s case, the hospital determined that questionable stent placement procedures were conducted on nearly 600 patients.<sup>18</sup> Further, the hospital discovered that Dr. Midei had evaded notice during various internal reviews because he was allowed to submit cases of his choosing for those reviews.<sup>19</sup> In December 2009, the hospital contacted 585 of the impacted patients and informed them that the stent procedure performed on them may have been unnecessary.<sup>20</sup> In January 2010, the first impacted patient lawsuit was filed against Dr. Midei and the hospital.<sup>21</sup> The Maryland state authorities launched an investigation, leading to newly proposed laws and

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<sup>12</sup> See *id.* “The United States also contends that AstraZeneca violated the federal Anti-Kickback Statute by offering and paying illegal remuneration to doctors it recruited to serve as authors of articles written by AstraZeneca and its agents about the unapproved uses of Seroquel. AstraZeneca also offered and paid illegal remuneration to doctors to travel to resort locations to ‘advise’ AstraZeneca about marketing messages for unapproved uses of Seroquel, and paid doctors to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel. The United States contends that these payments were intended to induce the doctors to prescribe Seroquel for unapproved uses in violation of the federal Anti-Kickback Statute.” *Id.*

<sup>13</sup> Robert Little, *Doctor Evaded Peer Review; Cardiologist Accused of Placing Unneeded Stents Also Picked Cases to be Checked*, BALT. SUN, May 29, 2010, at A1.

<sup>14</sup> See *id.* A stent is a flexible mesh tube placed in an artery to ensure the artery remains open. See generally Emily Mullin, *More Baltimore-area docs may have implanted unnecessary stents, lawyer says*, BALT. BUS. J., Oct. 5, 2010.

<sup>15</sup> Little, *supra* note 13.

<sup>16</sup> *Id.*

<sup>17</sup> See *id.*

<sup>18</sup> *Id.* “After reviewing ‘nearly 2,000’ of Midei’s cases - a number that hospital officials had not disclosed - reviewers found questionable stents in 585 patients, or about every third or fourth case.” *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> See generally Gary Haber, *St. Joseph Medical Center sued Over Stent Implant*, BALT. BUS. J., Jan. 22, 2010.

procedures to combat health care fraud.<sup>22</sup> As of October 2010, 101 individual and single class action lawsuits have been filed in this matter.<sup>23</sup> Finally, the Maryland Board of Physicians charged Dr. Midei with performing unnecessary medical procedures.<sup>24</sup>

Congress also increased its commitment to eradicating health care fraud. Senator Kristen Gillibrand of New York offered legislation, which opined that Medicare and Medicaid fraud cost the United States economy more than \$80 billion and the taxpayers of New York more than \$5 billion alone.<sup>25</sup> Spending measures passed by Congress for Fiscal Year 2011 authorized \$1.7 billion to combat fraud, waste, and abuse in health care.<sup>26</sup> An additional \$561 million was added late in the budget season to further bolster these activities.<sup>27</sup>

The Office of Inspector General for the United States Department of Health and Human Services (“OIG”) has been busy on these issues as well. In Fiscal Year 2010, OIG received civil monetary penalties for twenty-three fraud or fraudulent claims cases and fourteen kickback cases.<sup>28</sup> These cases resulted in over \$19 million in civil monetary penalties for the OIG in a single year.<sup>29</sup>

It is clear that the government significantly raised the stakes for health care providers participating in Federal health care programs. While the two examples above are related to large corporations, all entities submitting claims to Medicare, Medicaid, and other similar programs are vulnerable to attack. Under such intense scrutiny, how can a health care provider possibly navigate a new, highly charged environment?

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<sup>22</sup> Scott Graham, *Md. Health Care Chief Calls for Law, Policy Changes in Response to Stents Query*, BALT. BUS. J., Sept. 22, 2010. “John M. Colmers, the secretary of the state’s Department of Health and Mental Hygiene, calls for new laws that would allow Maryland’s health care agencies to share more information with each other, give Maryland’s physicians board greater leeway to investigate complaints against providers and slow the flow of some information being investigated from being shared with the public.” *Id.*

<sup>23</sup> See Mullin, *supra* note 14.

<sup>24</sup> *Id.*

<sup>25</sup> Cong. Documents, Gillibrand Announces New Legislation to Reduce and Fraud in Medicare and Medicaid, Protect Health Care for Seniors, Save Taxpayers Billions (July 13, 2010), available at 2010 WLNR 14089959.

<sup>26</sup> *Off-Label Marketing Continues as Priority for Federal Fraud Enforcement*, FDA Wk., Aug. 20, 2010.

<sup>27</sup> *Id.* \$376 million would go to the Centers for Medicare/Medicaid Services program integrity activities, \$95 million would go the Office of the Inspector General for Health and Human Services and \$90 million would go to the Department of Justice. See *id.*

<sup>28</sup> See *False and Fraudulent Claims*, U.S. DEP’T OF HEALTH & HUMAN SERV.: OFFICE OF INSPECTOR GEN., [http://oig.hhs.gov/fraud/enforcement/cmp/false\\_claims.asp](http://oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp) (last visited Nov. 19, 2010); See also *Kickback and Physician Self-Referral*, U.S. DEP’T OF HEALTH & HUMAN SERV.: OFFICE OF INSPECTOR GEN., <http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp> (last visited Feb. 2, 2011).

<sup>29</sup> See *id.*

This Article discusses a systematic approach to building a compliance program which can survive the aggressive prosecution of health care fraud. Part I explores the False Claims Act, which is used as the basis to prosecute health care fraud.<sup>30</sup> Part II considers the Fraud Enforcement and Recovery Act of 2009, which updated the False Claims Act and is the basis for intense prosecution.<sup>31</sup> Part III examines Corporate Integrity Agreements and requirements found in most of those documents.<sup>32</sup> Finally, part IV outlines what a strong compliance program should look like.<sup>33</sup> Ultimately, this Article concludes that the most effective compliance program uses the tools already outlined by the federal government to protect the corporation, its executives, and its shareholders.<sup>34</sup>

### I. THE FALSE CLAIMS ACT

The False Claims Act is the popular title for a series of statutes restricting fraudulent activity against the federal government. First, the most commonly known provision of the law makes it illegal to present, or cause to be presented, fraudulent claims for payment or approval to federal government employees or members of the military.<sup>35</sup> The law makes it illegal to make, use, or cause to be used false records or statements material to a fraudulent claim,<sup>36</sup> have control or possession of government money or property and deliver less than the full amount to the government,<sup>37</sup> defraud the government by acknowledging receipt of government property when the property was not received,<sup>38</sup> buy or accept a promise to buy government property from an improper source,<sup>39</sup> or

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<sup>30</sup> See *infra* Part I.

<sup>31</sup> See *infra* Part II.

<sup>32</sup> See *infra* Part III.

<sup>33</sup> See *infra* Part IV.

<sup>34</sup> See *infra* Part V.

<sup>35</sup> False Claims Act (Lincoln Law), 31 U.S.C. § 3729(a)(1)(A) (2010) (stating it a federal crime for any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. . .”).

<sup>36</sup> 31 U.S.C. § 3729(a)(1)(B) (stating it is illegal for any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .”).

<sup>37</sup> 31 U.S.C. § 3729(a)(1)(D) (stating it is unlawful for any person who “has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property . . .”).

<sup>38</sup> 31 U.S.C. § 3729(a)(1)(E) (stating that the law is violated when a person “is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true . . .”).

<sup>39</sup> See *id.* The law creates a prohibition for anyone who “knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property . . .” *Id.*

commit conspiracy to violate any of the aforementioned provisions.<sup>40</sup> Any person or entity violating the law was liable for a civil penalty of no less than \$5,000 or no more than \$10,000, plus three times the damages incurred by the government.<sup>41</sup> Interestingly, a provision in the law allowed the ruling court to reduce the treble damages to double damages if the person or entity who violated the law notified the government within 30 days of obtaining the information, the person or entity fully cooperated with the government investigation, and there was not a pending legal action already filed.<sup>42</sup>

## II. FRAUD ENFORCEMENT AND RECOVERY ACT OF 2009

In response to the financial crisis which began in 2008, Congress passed the Fraud Enforcement and Recovery Act of 2009 ("FERA").<sup>43</sup> The law, which passed on May 20, 2009,<sup>44</sup> made several changes to several existing laws. The most substantive overall change amended the criminal code to define terms related to the mortgage industry, the Troubled Asset Relief Plan, and the securities industry.<sup>45</sup> The most important change for the health care industry revolved around two changes, though. The False Claims Act was amended to expand liability for making false or fraudulent claims to the federal government<sup>46</sup> and

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<sup>40</sup> *See id.*

<sup>41</sup> *See id.*

<sup>42</sup> *See id.* The law allows this exception when: "(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information; (B) such person fully cooperated with any Government investigation of such violation; and (C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation." *Id.*

<sup>43</sup> Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (to be codified at 31 U.S.C. 3729).

<sup>44</sup> *Id.*

<sup>45</sup> *See id.* Specifically, the law amends the federal criminal code to include within the definition of "financial institution" a mortgage lending business or any person or entity that makes, in whole or in part, a federally related mortgage loan. Next, it defines "mortgage lending business" as an organization that finances or refinances any debt secured by an interest in real estate, including private mortgage companies and their subsidiaries, and whose activities affect interstate or foreign commerce. Third, it extends the prohibition against making false statements in a mortgage application to employees and agents of a mortgage lending business. Fourth, applies the prohibition against defrauding the federal government to fraudulent activities involving the Troubled Asset Relief Program (TARP) or a federal economic stimulus, recovery, or rescue plan. Fifth, it expands securities fraud provisions to cover fraud involving options and futures in commodities. Sixth, it expands the concept of monetary proceeds, for purposes of enforcing prohibitions against money laundering, to include gross receipts. *See id.*

<sup>46</sup> *See id.*

applied liability for presenting a false or fraudulent claim for payment or approval to anyone, which were previously limited to just federal employees and military officers.<sup>47</sup> Another addition now requires persons who violate the law to reimburse the federal government for the costs of a civil action to recover penalties or damages.<sup>48</sup> Finally, the new law expanded the ability of the government to intervene in *qui tam* actions brought by whistleblowers against companies defrauding the government.<sup>49</sup>

### III. WHAT IS A CORPORATE INTEGRITY AGREEMENT?

Even if a health care company is successful in evading liability under the False Claims Act, a Corporate Integrity Agreement (“the Agreement”) may still be necessary to resolve outstanding issues. Corporate Integrity Agreements are agreements between the OIG and entities that may have been liable for defrauding the government in federal health care program transactions such as Medicare and Medicaid.<sup>50</sup> These agreements generally place nine major requirements on the participant: (1) a Compliance Committee; (2) internal audit and review processes; (3) developing and implementing a Code of Conduct; (4) developing and implementing policies and procedures; (5) developing and implementing training; (6) retaining an Independent Review Organization; (7) developing and implementing an Employee Disclosure Program; (8) screening and removing ineligible persons; (9) and filing incremental reports.<sup>51</sup> Please note that Corporate Integrity Agreements are intricate documents containing extensive boilerplate language. This Article takes a high level view of the standard document and is clear that there may be unique requirements or language in some documents.

#### A. Compliance Officer/Compliance Committee

One of the first requirements discussed in a Corporate Integrity Agreement is a Compliance Committee. First, the Agreement calls for a defined Compliance Officer position, with specified responsibilities,

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<sup>47</sup> Compare 31 U.S.C.A. § 3729(a)(1) (2009) (“Any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . .”), with 31 U.S.C.A. § 3729(a)(1) (2008) (“Any person who knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . .”).

<sup>48</sup> See Fraud Enforcement and Recovery Act § 4(a)(3), 123 Stat. at 1622.

<sup>49</sup> See *id.*

<sup>50</sup> *Corporate Integrity Agreements*, U.S. DEP’T OF HEALTH AND HUMAN SERV., OFFICE OF INSPECTOR GEN., <http://oig.hhs.gov/fraud/cias.asp> (last visited Nov. 9, 2010).

<sup>51</sup> *Corporate Integrity Agreement Between the Office of the Inspector General of the United States Department of Health and Human Services and A&C Health Care Services, Inc.*, U.S. DEP’T OF HEALTH AND HUMAN SERV., OFFICE OF INSPECTOR GEN., 1 (Jan. 4, 2008), [http://oig.hhs.gov/fraud/cia/agreements/a\\_c\\_health\\_care\\_services\\_inc\\_01042008.pdf](http://oig.hhs.gov/fraud/cia/agreements/a_c_health_care_services_inc_01042008.pdf).



including: developing and implementing policies and procedures, being a member of senior management, making reports directly to the Board of Directors, being authorized to report any issue directly to the Board of Directors, and requiring superiority over the General Counsel or Chief Financial Officer.<sup>52</sup> Second, the Agreement calls for the creation of a Compliance Committee and affirmative action by the Board of Directors, which may include forming a standing committee or passage of a resolution.<sup>53</sup> Finally, these actions all must be achieved within a stated timeframe, usually within 120 days of execution of the Agreement.<sup>54</sup>

### B. Internal Audit and Review Processes

Another major requirement of the Agreement requires signatories to develop and implement an internal auditing process.<sup>55</sup> Generally, the internal audit process examines quality of care issues, whether policies and procedures are followed, and whether training offered to staff and all obligations of the Agreement are being met.<sup>56</sup> This requirement usually must be implemented within 90 days.<sup>57</sup>

### C. Developing and Implementing a Code of Conduct

Third, signatories are required to develop and implement a Code of Conduct.<sup>58</sup> The Code of Conduct, at a minimum, must reflect the company's and employees' willingness to comply with federal health care program requirements; employee obligations and rights under the Employee Disclosure Program; and consequences of an employee's failure to report.<sup>59</sup> The Agreement also requires all employees to certify in writing that they have received, read, understood, and will abide by the

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<sup>52</sup> See, e.g., *Corporate Integrity Agreement Between the Office of the Inspector General for the United States Department of Health and Human Services and Boston Scientific Corporation*, OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, 4-5 (2009), [http://oig.hhs.gov/fraud/cia/agreement/boston\\_scientific\\_corporation\\_12232009.pdf](http://oig.hhs.gov/fraud/cia/agreement/boston_scientific_corporation_12232009.pdf) (last visited Nov. 8, 2010).

<sup>53</sup> See *id.* at 5.

<sup>54</sup> See *id.*

<sup>55</sup> See, e.g., *Corporate Integrity Agreement Between the Office of the Inspector General for the United States Department of Health and Human Services and Cathedral Rock Corporation, et al.*, U.S. DEP'T HEALTH AND HUMAN SERV., OFF. OF THE INSPECTOR GEN., 4 (2010), [http://oig.hhs.gov/fraud/cia/agreements/cathedral\\_rock\\_01062010.pdf](http://oig.hhs.gov/fraud/cia/agreements/cathedral_rock_01062010.pdf) (last visited Nov. 8, 2010).

<sup>56</sup> See *id.* at 4-5.

<sup>57</sup> See *id.* at 4.

<sup>58</sup> See, e.g., *Corporate Integrity Agreement Between the Office of the Inspector General for the United States Department of Health and Human Services and Interdent, Inc., et al.*, U.S. DEP'T HEALTH AND HUMAN SERV., OFF. OF THE INSPECTOR GEN., 4 (June 20, 2008), [http://oig.hhs.gov/fraud/cia/agreements/InterDent\\_inc\\_06202008.pdf](http://oig.hhs.gov/fraud/cia/agreements/InterDent_inc_06202008.pdf) (last visited Nov. 8, 2010).

<sup>59</sup> See *id.* at 4-5.

Code of Conduct.<sup>60</sup> In most Agreements, this requirement must be implemented within 90 days of execution.<sup>61</sup>

*D. Develop and Implement Policies and Procedures*

Fourth, the Agreement requires the development and implementation of policies and procedures.<sup>62</sup> These policies and procedures must discuss the issues covered in the Code of Conduct, the operation of the company's compliance program, compliance with federal health care programs, the restriction against hiring or contracting with excluded persons or entities, and any other issues which initially led to the Agreement.<sup>63</sup> The required policies and procedures usually must be implemented within 90 days of execution.<sup>64</sup>

*E. Develop and Implement Staff Training*

Fifth, the Agreement requires the signatories to implement training for all staff, Executives, and the Board of Directors.<sup>65</sup> The training is split into two separate categories: General and Specific.<sup>66</sup> Generally, the General Training is an hour in length and covers the Agreement requirements, the signatory's Compliance Program, and the issues which led to the Agreement.<sup>67</sup> General Training must be offered to all staff including management and the Board of Directors, usually within 90 or 120 days of execution, and requires written certification from each trainee.<sup>68</sup> Specific Training is technical in nature and for a smaller universe of employees.<sup>69</sup> Specific Training discusses in-depth federal health care program issues, relevant policies and procedures, and business

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<sup>60</sup> *Id.* at 5.

<sup>61</sup> *Id.* at 4-5.

<sup>62</sup> U.S. DEP'T HEALTH AND HUMAN SERV., *Corporate Integrity Agreement Between the Office of the Inspector General for the United States Department of Health and Human Services and Grant Park Nursing Home Limited Partnership d/b/a Grant Park Care Center and Grant Park Management, LLC*, OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUM. SERVICES 5 (2008), [http://oig.hhs.gov/fraud/cia/agreements/grant\\_park\\_08292008.pdf](http://oig.hhs.gov/fraud/cia/agreements/grant_park_08292008.pdf) (last visited Feb. 2, 2011).

<sup>63</sup> *Id.* at 6-8.

<sup>64</sup> *Id.* at 5, 9.

<sup>65</sup> U.S. DEP'T HEALTH AND HUMAN SERV., *Corporate Integrity Agreement Between Office of Inspector General for the Department of Health and Human Services and Jazz Pharmaceuticals, Inc.*, OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUM. SERVICES 5 (2007), <http://oig.hhs.gov/fraud/cia/agreements/Jazz%20CIA.pdf> (last visited Feb. 2, 2011).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

specific issues.<sup>70</sup> Specific Training must be implemented within 90 days of execution and also requires written certification from each trainee.<sup>71</sup>

*F. Retain an Independent Review Organization/Monitor*

Signatories are required to retain an Independent Review Organization (“IRO”).<sup>72</sup> The IRO must be an accounting, auditing, or consulting firm and have expertise in billing, coding, reporting, and at least the general requirements of federal health care programs.<sup>73</sup> The IRO is required to evaluate and analyze the signatory’s coding, billing, federal health care program claims submission and reimbursements.<sup>74</sup> The evaluation and analysis exercise is heavily scripted in the Agreement, and at least in the first year, the IRO must also complete an analysis of whether the signatory sought certain unallowable costs over the course of the year.<sup>75</sup>

*G. Develop and Implement an Employee Disclosure Program*

A sixth major requirement under the Agreement is for the signatory to develop and implement an Employee Disclosure Program.<sup>76</sup> The Employee Disclosure Program is composed of a mechanism to allow an employee to disclose to someone other than the employee’s chain of command, issues or questions related to potential criminal, civil, or administrative violations of Medicare or Medicaid statutes and regulations.<sup>77</sup> The program must develop and implement a policy emphasizing that employees will not face retaliation or harassment for disclosing potential violations.<sup>78</sup> Additionally, the program must allow for anonymous disclosure communications and be implemented generally within 90 days.<sup>79</sup> Finally, the Agreement obligates the Compliance

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<sup>70</sup> *Id.*

<sup>71</sup> See OFF. OF THE INSPECTOR GEN., U.S. DEP’T OF HEALTH AND HUM. SERVICES, *supra* note 65.

<sup>72</sup> U.S. DEP’T HEALTH AND HUMAN SERV., *Corporate Integrity Agreement Between Office of Inspector General for the Department of Health and Human Services and Kohal Pharmacy, Inc.*, OFF. OF THE INSPECTOR GEN., U.S. DEP’T OF HEALTH AND HUM. SERVICES 5 (June 21, 2007), [http://oig.hhs.gov/fraud/cia/agreements/kohal\\_pharmacy\\_inc\\_06212007.pdf](http://oig.hhs.gov/fraud/cia/agreements/kohal_pharmacy_inc_06212007.pdf) (last visited Feb. 2, 2011).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> U.S. DEP’T HEALTH AND HUMAN SERV., *Corporate Integrity Agreement Between Office of Inspector General for the Department of Health and Human Services and M.A.C.T. Health Board, Inc.*, OFF. OF THE INSPECTOR GEN., U.S. DEP’T OF HEALTH AND HUM. SERVICES 5 (2007), [http://oig.hhs.gov/fraud/cia/agreements/MACT\\_health\\_board\\_inc12172007.pdf](http://oig.hhs.gov/fraud/cia/agreements/MACT_health_board_inc12172007.pdf) (last visited Feb. 2, 2011).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

Officer to maintain disclosure logs and make a good faith effort to investigate all disclosures.<sup>80</sup>

#### *H. Screen and Remove Ineligible Persons*

A seventh major requirement in the Agreement centers on ineligible persons.<sup>81</sup> The Agreement defines ineligible persons as anyone currently debarred, suspended, or excluded from participating in federal health care programs or who has a pending conviction for fraud that had not yet resulted in debarment, suspension, or exclusion.<sup>82</sup> The Agreement requires the signatory to ensure all employees are not ineligible, that they are screened against the two federal ineligibility databases, and implement a policy requiring employees to disclose debarment, exclusion, or suspension immediately.<sup>83</sup> The Agreement finally requires the removal of any ineligible person from participating in or around federal health care programs attached to the signatory.<sup>84</sup> In most cases, this must be implemented within 90 days of execution.<sup>85</sup>

#### IV. INCREMENTAL REPORTING

The eighth and final major requirement is the submission of incremental reports.<sup>86</sup> Specifically, the signatory must submit an Implementation Report within six months of execution that outlines progress against Agreement obligations to that point.<sup>87</sup> Within 14 months of execution, an Annual Report must be submitted to the OIG with specified information and statistics.<sup>88</sup> Subsequently, Annual Reports are due on the anniversary of the original Annual Report due date.<sup>89</sup>

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<sup>80</sup> *Id.*

<sup>81</sup> See U.S. DEP'T HEALTH AND HUMAN SERV., *Corporate Integrity Agreement Between Office of Inspector General for the Department of Health and Human Services and McAllen Hospitals, L.P. d/b/a South Texas Health System*, (2009), [http://oig.hhs.gov/fraud/cia/agreements/marshall\\_fire\\_protection\\_district\\_ambulance\\_and\\_rescue\\_service\\_03312008.pdf](http://oig.hhs.gov/fraud/cia/agreements/marshall_fire_protection_district_ambulance_and_rescue_service_03312008.pdf) (last visited Feb. 2, 2011).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* at 17.

<sup>85</sup> *Id.*

<sup>86</sup> See U.S. DEP'T HEALTH AND HUMAN SERV., *Corporate Integrity Agreement Between Office of Inspector General for the Department of Health and Human Services and Marshall Fire Protection District Ambulance and Rescue Service*, (2008) [http://oig.hhs.gov/cia/agreements/marshall\\_fire\\_protection\\_district\\_ambulance\\_and\\_rescue\\_service\\_03312008.pdf](http://oig.hhs.gov/cia/agreements/marshall_fire_protection_district_ambulance_and_rescue_service_03312008.pdf) (last visited Feb. 2, 2011).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 18-20.

<sup>89</sup> *Id.* at 20-21.

V. HOW CAN A HEALTH CARE COMPANY IMMUNIZE ITSELF IN THIS NEW, AGGRESSIVE ENVIRONMENT?

Before discussing a defensive strategy, there are two important assumptions that have to be made. First, how serious is the company about compliance? Compliance programs take organization, dedication, and resources. If a company has a half-hearted approach to implementing compliance efforts and does not provide the necessary supports, it may create the perception that any questionable behavior was purposeful. The second assumption is that an organization is not obligated under an existing settlement agreement with either a public or private entity which dictates the elements of a compliance program.

It is my belief that utilizing the government's existing response to health care fraud is the best defense to aggressive prosecution. Specifically, by dissecting standard Corporate Integrity Agreement requirements and implementing some provisions in advance as part of an overall compliance strategy, a health care company can somewhat immunize itself from fraud allegations and the expense accompanying investigations and settlements. Further, I believe there are five specific areas of the Corporate Integrity Agreement that can be the anchor for a good compliance program: the Compliance Officer, developing and implementing an Employee Disclosure Program, training, screening process for ineligible persons, and internal and external audit processes.

*A. Hire a Professional Compliance Officer*

Virtually every Corporate Integrity Agreement requires a participating entity to hire a Compliance Officer and/or Compliance Committee.<sup>90</sup> Under the Corporate Integrity Agreement, the Compliance Officer is responsible for assessing risk, implementing policies and procedures, monitoring internal and external audits, and reporting to the Executive Committee, Board of Directors, and Health and Human Services.<sup>91</sup>

There are many different position descriptions for a Compliance Officer. However, ideally, I believe there are six important job responsibilities. First, the position should have unfettered access to all aspects of the corporation. Second, the position should review all policies and procedures and make recommendations for modifications or improvements. Third, the position should be responsible for all investigations and recommendations related to policy and procedure violations. Fourth, all compliance education and training should be vested in the position. Fifth, the Compliance Officer should not have any

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<sup>90</sup> See U.S. DEP'T HEALTH AND HUMAN SERV., *Corporate Integrity Agreements Document List*, OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUM. SERV., [http://oig.hhs.gov/fraud/cia/cia\\_list.asp](http://oig.hhs.gov/fraud/cia/cia_list.asp) (last visited Feb. 2, 2011).

<sup>91</sup> See *supra* note 52 and accompanying text.

duties other than compliance. There is a lengthier discussion on this subject later in this section.<sup>92</sup> Finally, the position should issue quarterly reports to the Executive Committee and the Board of Directors on compliance issues and risk assessments.

Next, who fills the position and to whom do they report? In many corporations, the Compliance Officer is the General Counsel or the Chief Financial Officer.<sup>93</sup> There are a few problems with another member of the executive staff undertaking the duties of a Compliance Officer. First, an executive staff member already has significant responsibilities and obligations. Managing a compliance program is a full-time job all unto itself. One issue the government could easily raise in investigating a Corporate Compliance Program is that the program, as implemented by the company, is not a priority because it is simply rolled into another corporate function.

A second, larger issue is a question of independence and objectivity. Specifically, the General Counsel has an attorney-client relationship with the corporation and generally serves in an advisory capacity.<sup>94</sup> Imagine that General Counsel advises the corporation against implementing a policy, which may negatively impact its compliance with federal health care law. Subsequently, the General Counsel is expected to implement said policy, measure compliance, and then possibly defend the corporation in an investigation. Obviously, such a real scenario raises a number of ethical and legal issues.

The situation does not look more promising for the Chief Financial Officer. Imagine the Chief Financial Officer implements a financial policy which negatively impacts the corporation's compliance with federal health policies and regulations. The corporation lacks an independent voice to question the legality of the policy implementation.

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<sup>92</sup> See *infra* notes 94-95 and accompanying text.

<sup>93</sup> JONATHAN SMITH & CO., <http://www.jonathansmith.com/anne.cfm> (last visited Nov. 6, 2010) (Jonathan Smith merges Chief Compliance Officer and Chief Financial Officer); MEDQUIST, <http://www.medquist.com/Default.aspx?tabid=132> (last visited Nov. 6, 2010) (MedQuist merges Chief Compliance Officer and General Counsel); NAVIGATORS GROUP, INC., <http://www.navg.com/Pages/mngmnt-team-detail.aspx?EmpId=102> (last visited Nov. 6, 2010) (Navigators Group merges Chief Compliance Officer and General Counsel); REDWOOD INVESTMENTS, [http://www.redwoodinv.com/Redwood\\_Investments/Steven\\_T\\_Flammey.html](http://www.redwoodinv.com/Redwood_Investments/Steven_T_Flammey.html) (last visited Feb. 2, 2011) (Redwood Investments merges Chief Compliance Officer and General Counsel).

<sup>94</sup> See MODEL RULES OF PROF'L CONDUCT R. 1.13 (2007); RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS § 96 (2000). The Restatement and the model code, while not binding on any jurisdiction, each serve as persuasive models of the rules of ethics which have provided guidelines and advice for states in the creation and interpretation of their ethical codes. There is little case law, controlling on a national scale, the scope of the attorney and corporation-client privilege as the interpretation of state ethical codes is left to the states themselves. Cf. *Upjohn Co. v. U.S.*, 449 U.S. 383, 389 (1981) (holding that the scope of corporation's privilege decided on the grounds of federal common law).

This would raise a red flag for any investigator. Based on those arguments, the Compliance Officer should be an independent employee.

The next step is to determine the reporting chain for the Compliance Officer. Based on the previous argument, it does not make legal or practical sense for the Compliance Officer to report to the General Counsel or the Chief Financial Officer. Most other executive staff members would have similar conflicts as the General Counsel or the Chief Financial Officer because of their existing day-to-day responsibilities. Thus, the best option would be for the position to not be an executive member of the organization, but report directly to the Chief Executive Officer and/or the Board of Directors. The Executive Committee is vested with issues like profitability, which should not be within the Compliance Officer's scope. Further, a strong argument could be made that the Compliance Officer should report to the Board of Directors because they are not involved in the day-to-day management of the business. Regardless, the Compliance Officer should report to the top of the corporation's management.

A strongly defined, independent Compliance Officer is evidence that a corporation takes the compliance function seriously and is the first element of a strong compliance program. If the Compliance Officer is in a weakened position, it stands to reason that the program the individual manages would also be perceived as weak.

#### *B. Develop and Implement an Employee Disclosure Program*

Another provision in Corporate Integrity Agreements calls for the development and implementation of an Employee Disclosure Program.<sup>95</sup> An Employee Disclosure Program is a policy and procedural mechanism for employees to report what they believe is illegal or immoral behavior within the organization.<sup>96</sup> These programs also protect employees who make disclosures against any form of retaliation by the corporation such as harassment or demotion. Also, under a Corporate Integrity Agreement, the Compliance Officer is required to develop and maintain a log of complaints, which records the complaint, the reporting source, and the disposition of the complaint.<sup>97</sup> The Compliance Officer also coordinates the investigation of each complaint. The reporting mechanism must be advertised openly and liberally to all employees. Finally, a list of reporting outlets must be made available to employees, usually beyond their chain of command. These sources usually include the Compliance Officer, the State Inspector General, and the OIG.

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<sup>95</sup> See *supra* text accompanying note 76.

<sup>96</sup> See *supra* text accompanying note 77-79.

<sup>97</sup> See *supra* text accompanying note 80.

Developing and implementing an Employee Disclosure Program is a key component in a corporation's defense strategy. Many *qui tam* plaintiffs tell the same story. They observed wrongdoing of some sort in the workplace and reported it to their supervisor or someone else in their chain of command. Once they reported it, they were either ignored or harassed for disclosing the acts in question. While developing such mechanisms is seemingly uncomfortable for many corporations, the rationale for such a program is simple. The simple answer is that it may cost the corporation and may have significant ramifications. If a corporation has nothing to hide, it would be ideal to have every employee invested in protecting the corporation from malfeasance. Imagine a manager in a nursing home had an agreement with a respiratory therapist whereby the respiratory therapist would submit claims to Medicare, but would not actually provide service to the patients. The manager agreed to verify the services as part of the nursing home's treatment plan for its patients. Imagine further a subordinate discovered the deception and failed to disclose because the employee feared for his job. Finally, consider a patient who actually needed respiratory therapy is denied the service because of the deceptive agreement between the respiratory therapist and the manager. The level of liability and risk for the corporation in the scenario is grave. In any investigation, it will be clear that the failure to disclose may have been remedied if the employee could have disclosed against the manager.

How would the Employee Disclosure Program be implemented? First, I would suggest hiring a third party vendor to provide an external 800 telephone number and to actually log disclosures. After logging the disclosures, the vendor would forward all the relevant information to the Compliance Officer for investigation and disposition. Utilizing such a vendor would inspire confidence in the system and ensure the recording of the information is uncompromised. The Disclosure Program policies should be clear as to all of the steps of the investigation, report generation, and disposition of a disclosure. The policy should also outline the process for ensuring the discloser is protected from any form of disciplinary action for disclosing. Finally, the policies must be communicated in a clear and concise manner in every form and medium available to the corporation. This includes email, open forums, posters, announcements, and presentations at staff meetings and phone trees. It is important that all modes of communication are used because a logical question during a False Claims Act investigation may be how were employees alerted about the Disclosure Program. The ability to show constant communication about the Disclosure Program may prove to be invaluable. If one believes the philosophy that the best defense is a good defense, the use of a Disclosure Program is a custom made support.



### C. Training

Compliance training for all employees is the next provision in the strategy.<sup>98</sup> As previously noted, Corporate Integrity Agreements require participants to offer training to all employees.<sup>99</sup> Building a solid compliance program requires a competent training program.

So, what kind of training is needed? All employees should be trained on the company's overall compliance program, the False Claims Act, Employee Disclosure Program, and the consequences of being an excluded person. Training should be held at least on an annual basis and also be encompassed in any new employee orientation.

For those employees in claims reimbursement positions, it is critical that they receive the above-referenced training as well as Medicare and Medicaid training. Given the intense scrutiny that claim submissions are receiving from the Centers for Medicare and Medicaid Services, it is crucial that this training be offered on a quarterly basis. Part of the strategy articulated in this Article is predicated on building a compliance program that is risk adverse.

Who should offer the training and how should it be delivered? Seemingly, there is no need to bring in specialized consultants or trainers. This Article has advised hiring a professional Compliance Officer, and that individual can train the staff. Also, it is an excellent opportunity to acquaint the staff with the Compliance Officer and allow them to ask questions. As for delivery, there are many available options including online training. What is most important is that training is offered and made mandatory for the staff.

### D. Screening of Ineligible Persons

Corporate involvement of an ineligible person in a health care company will inspire investigations by the OIG or the Department of Justice. As noted above, once a company is under a Corporate Integrity Agreement, it is restricted from allowing any ineligible individual from working on behalf of the company in or around federal health care programs.<sup>100</sup>

The company should screen all employees and contractors to ensure that they are not ineligible persons. Someone who is deemed ineligible has already been involved in fraud or other malfeasance and could compromise the company. It is important to note that contractors, regardless of the service provided on behalf of the company, create as much risk for the company as an employee and should not be treated any

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<sup>98</sup> See *supra* text accompanying notes 65-71.

<sup>99</sup> See *supra* text accompanying note 68.

<sup>100</sup> See *supra* text accompanying notes 81-85.

differently. These screenings should happen at least on an annual basis and during the pre-hire process.

In addition, the company should also implement policies which require all employees and contractors to notify the company if they are ever served a Notice of Exclusion. Imagine a nurse is employed in a hospice. While working there, she is implicated in a Medicaid fraud scheme. Before the matter is settled, the nurse quits her job and takes a job working in an urgent care clinic. Under the scenario, assume the urgent care clinic screens all employees for ineligibility during the pre-hire process and on an annual basis. During her pre-hire process, the nurse was screened for ineligibility, but was not implicated because the matter was still pending. Six months after starting her employment with the urgent care clinic, the matter is resolved and, as a result, the nurse is served a Notice of Exclusion. If the urgent care clinic did not know the nurse was excluded, she would continue working, unabated, for six months until the next round of screenings were conducted. The scenario merely underscores why the policy is essential.

Also, it is pivotal that regardless of an individual's position within a company, they must be screened and, if they are found to be ineligible, removed or activities highly restricted. It is not uncommon for owners or executives of health care companies to be implicated in malfeasance and then excluded.<sup>101</sup> These individuals either start companies under new names or simply move on to another company.<sup>102</sup> Regardless of the position the individual holds with the company, they are still excluded and their activities must be carefully managed or the company risks extreme exposure.

#### *E. Internal and External Audit Processes*

The final defensive strategy is to have strong internal and external audit processes. First, the company should implement a robust internal audit process. Depending on the company's size, the internal audit should be conducted at least quarterly and result in a written report summarizing the audit sample, the findings, and recommendations for improvements. As described earlier, the Compliance Officer should be designated coordinator for the audit. Additionally, there should be a management response to the report which clearly and concisely responds to the audit's findings.

The external audit process should mirror the internal process and be conducted on at least an annual basis. Just as with the internal audits, the external audits should result in a final report which includes a

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<sup>101</sup> See Markon, *supra* note 5, at 2.

<sup>102</sup> Cf. OFF. OF THE INSPECTOR GEN., MEDICARE PAYMENTS TO OIG EXCLUDED PHYSICIANS 1-2 (2000).

management response to each finding. While it may seem obvious, the credentials of the auditing firm must be above reproach. It is important to note that the credibility of the audit rests on the credibility, independence, and objectivity of the auditors.

## VI. CONCLUSION

In April 2010, the Maryland General Assembly, in concert with the Office of the Governor and Maryland Hospital Association, passed the Maryland False Claims Act ("MFCFA").<sup>103</sup> The act mirrors similar regulations at the federal level introduced originally by the federal False Claims Act, which are discussed at length above.<sup>104</sup> With the passage of MFCFA, Maryland has joined several other states in recognizing that fighting health care fraud at the federal level has its limits, in that only larger, more global cases are usually prosecuted.<sup>105</sup> These state acts, like the MFCFA, empower state regulatory agencies with the necessary tools to fight fraud at a more localized level.<sup>106</sup> The passage of the MFCFA is expected to increase the recovery of Medicaid Funds that were lost to fraud, waste, or cost recoveries to as much as \$46.5 million in fiscal year 2011, an increase of nearly 75% over the current year's estimate of \$26.5 million.<sup>107</sup> Beyond granting expressed powers and procedures for state agencies in prosecuting fraud, the MFCFA provides explicit whistleblower protections to employees and requires employers to conspicuously provide notice of those protections to all employees.<sup>108</sup>

The federal government has also made it clear that it intends to become an aggressive player as it relates to health care fraud.<sup>109</sup> Under such intense scrutiny, a health care company must take a proactive approach to protect itself. The keys to developing a protection strategy can be found in the Corporate Integrity Agreements entered into by companies and individuals who have run afoul of the Department of Health and Human Services. There are five particular actions a company can take to protect itself: hire a professional, independent Compliance Officer, develop and implement an Employee Disclosure Program, training, screening for ineligible persons, and internal and external audit

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<sup>103</sup> Maryland Register Notice of SB 279, in April of 2010.

<sup>104</sup> Office of the Lt. Governor Anthony G. Brown, *Press Release: Maryland False Health Claims Act of 2010 Passes Final Vote in Maryland General Assembly*, April 9, 2010, <http://www.governor.maryland.gov/ltgovernor/pressreleases/100409.asp>.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> Department of Health and Mental Hygiene, *Press Release: Lt. Governor Brown Announces More than \$26 Million Recovered in FY2010 from Medicaid Fraud, Waste and Abuse*, July 22, 2010, <http://www.dhnh.state.md.us/pressreleases/2010/lgov072210.html>.

<sup>108</sup> MARYLAND CODE ANN., HEALTH-GEN. §§ 2-607-2-608. (2010).

<sup>109</sup> See *supra* notes 7-12 and accompanying text.

processes. If a health care company shows dedication to a robust compliance program, it can weather the gathering storm of fraud prosecution.