Published by *Life Sciences Law360* on May 27, 2014. Also ran in *Government Contracts Law360*, *Health Law360*, and *White Collar Law360*.

A Wake-Up Call For Cos. With Corporate Integrity Agreements

--By Marilyn May and Abraham Gitterman, Arnold & Porter LLP

Law360, New York (May 27, 2014, 9:45 PM ET) -- Over the last five years, the U.S. Department of Justice, through its Health Care Fraud Prevention and Enforcement Action Team (HEAT), has recovered $19.2 billion in health care-related fraud and abuse investigations, including actions under the federal False Claims Act, with more than $13.4 billion of that amount recovered in cases involving fraud against federal health care programs such as Medicare and Medicaid — a recovery rate of almost $8 for every $1 spent. In 2013 alone, the federal government recovered a record-breaking $4.3 billion in taxpayer dollars in fiscal year 2013, up from $4.2 billion in FY 2012.[1]

As part of the global resolution of these cases, many of the entities or individual health care professionals (HCPs) involved enter into corporate integrity agreements (CIAs) with the Office of Inspector General for the U.S. Department of Health and Human Services. Approximately 200 entities or individuals currently operate under a CIA.[2] The OIG claims CIAs are necessary and that billion-dollar settlements are not a sufficient deterrent to change corporate culture in pharmaceutical companies.[3] While some critics assert that CIAs, like criminal fines and civil penalties, are just the "cost of doing business" and have not effectively deterred or reformed health care providers, entities, or drug and device manufacturers,[4] Gregory Demske, chief counsel to the OIG, recently stated greater use of CIAs "can encourage organizations to make compliance a higher priority."[5]

Relators continue to file qui tam suits under the False Claims Act alleging various violations of the Food, Drug and Cosmetic Act, as well as the Anti-Kickback Statute (AKS) naming as defendants companies currently operating under CIAs. Such lawsuits raise the question: Will the OIG penalize or even exclude an entity already operating under a CIA if such allegations are proved or if there is a subsequent settlement?

HHS Actions for Breach of CIA Requirements

CIAs contain provisions allowing the OIG to penalize entities for failing to comply with the terms of the agreement. CIAs typically contain a stipulated penalty provision of up to $2,500 for each day the entity fails to: (1) implement a written code of conduct or policies and procedures; (2) conduct employee training; (3) fulfill certification obligations for certain employees and adopt resolutions by boards of directors; (4) submit reportable event information; or (5) implement certain monitoring and oversight programs.

The OIG can also exclude the applicable entity for a "material breach" of the CIA, typically defined as: (1) repeated or flagrant violation of CIA obligations; (2) failure to report a reportable event and take corrective action; (3) failure to engage and use an IRO; (4) failure to respond to a demand letter concerning the payment of stipulated penalties; and (5) failure of an entity's board of directors to issue a resolution regarding compliance with the CIA.

Although the OIG has rarely exercised its exclusion authority for material breach of a CIA,[6] in April 2014, it entered into a five-year exclusion agreement with Church Street Health Management (CSHM)

LLC, (a pediatric dental management chain providing dental services primarily to children on Medicaid) based on CSHM's alleged repeated material violations of its existing CIA.[7]

CHSM's corporate predecessor (FORBA Holdings) entered into a CIA in 2010,[8] as part of the resolution of an FCA case involving allegations that the company had provided dental services to children on Medicaid that were either medically unnecessary or failed to meet professionally recognized standards of care. According to the OIG, despite more than 90 site visits by an independent quality monitor, the OIG's imposition of financial penalties and forced divestiture of one of the company's clinics, "CSHM remained in material breach of its CIA."

On March 7, 2014, the OIG issued a notice of exclusion to CSHM based upon numerous alleged material breaches of its obligations under the CIA, including submitting a false certification from its compliance officer, as well as failure to: (1) report serious quality-of-care reportable events, take corrective action, or make appropriate notifications of those events to the State dental boards as required by the CIA; (2) implement and maintain key quality-related policies and procedures; (3) comply with internal quality and compliance review requirements; (4) properly maintain a log of compliance disclosures; and (5) perform training as required by the CIA.

In announcing the exclusion, HHS Inspector General Daniel Levinson noted that CSHM had "committed repeated and flagrant violations of its obligations under the CIA … that put quality of care and young patients' health and safety at risk."[9] He emphasized the exclusion underscored the OIG's "commitment to enforcing our integrity agreements designed to promote quality of care and protect patients in Federal health care programs."[10] The Inspector General further added that this exclusion "makes clear to the provider community that OIG closely monitors our CIAs, critically evaluates providers' representations and certifications, and will pursue exclusion actions against providers that fail to abide by their integrity agreement obligations."[11]

To minimize immediate disruption of care to the hundreds of thousands of children treated at CSHM clinics and to enable an orderly, controlled shutdown of the company or divestiture of its assets, the exclusion will be effective on Sept. 30, 2014. An independent monitor will continue to monitor the quality of care being provided to patients at CSHM clinics. CSHM is required to inform patients at least 30 days before closing a clinic. CSHM is also required to keep state Medicaid agencies abreast of developments and provide monthly status reports to the OIG. Any divestiture of assets by CSHM must be through bona fide, arms-length transactions to an entity that is not related to or affiliated with CSHM.

Although this is a rare instance of OIG exclusion of a provider for material breach of a CIA, based on the alleged facts it appears that the company continued to operate its business in the same manner that led to the False Claims Act litigation in the first place and continued to expose a vulnerable population of children to poor or unnecessary care. Additionally, according to the OIG press release, the OIG had attempted unsuccessfully to resolve issues with CHSM before issuing a notice of proposed exclusion.

In the absence of these aggravating factors, it is more likely that the OIG will impose stipulated penalties for breach of a CIA. The amount of such penalties and the frequency with which they are imposed, however, are difficult to ascertain. In a 2009 article, an OIG attorney reported that the OIG had assessed stipulated penalties against 41 providers and collected nearly $600,000 in penalties.[12] As this information does not appear on the OIG's website or in its annual reports, it is difficult to determine the total number and amounts of stipulated penalties.

There is some potential that stipulated penalties, reportable events, and other CIA violations will be made public as a result of litigation filed by consumer protection groups and plaintiff's lawyers in product liability actions. While some CIA documents have been made public under the Freedom of Information Act, others have been protected by FOIA Exemption 4, which covers trade secrets and financial information. Thus, ongoing litigation of these issues will be important to follow. However, courts have recognized in the past that documents provided in connection with CIAs "often include confidential or proprietary information" and that "a frequent concern raised by the subject entities during negotiation of the CIA is what type of protection the government will extend to the subject entity's confidential and proprietary information."[13]

In fact, the OIG itself has declared that if "the OIG were to release confidential proprietary information submitted under a CIA, subject entities under CIAs would 'be reluctant to submit complete information with their annual reports, thereby impairing the OIG's ability to monitor the CIAs,'" and such disclosure would "'severely impair' the OIG's ability to 'negotiate meaningful CIAs in the future.'"[14] As a result, the court held that disclosure of CIA documents "would impair the government's ability to secure voluntary execution of CIAs in [the] future."[15]

Overview of CIAs

The OIG negotiates CIAs with providers and other entities as part of the resolution of federal health care program investigations. The providers or other entities agree to the obligations in the CIA, in exchange, the OIG agrees not to seek exclusion from participation in federal health care programs. These agreements are usually referenced in the documents between the Department of Justice and the provider or entity resolving the underlying matter. The default duration for a CIA is five years — the minimum duration required for most mandatory exclusions.[16] Exclusions are often referred to as the "economic death penalty."[17] If excluded, the government is prohibited from making payment for any items or services billed to a federal healthcare program by the excluded individual or entity.

The OIG has statutory mandatory and permissive exclusion authority. Under its mandatory authority, the OIG must exclude any individual or entity from participation in any federal health care program if the individual or entity is convicted of: (1) a felony relating to health care fraud, (2) a program-related crime;[18] (3) an offense relating to patient abuse;[19] or (4) a felony relating to controlled substances.[20]

Under the OIG's permissive exclusion authority, the agency may in its discretion exclude an individual or entity "based on a host of lesser offenses and even affiliations with sanctioned entities."[21] For example, OIG can permissively exclude an individual[22] or entity for: (1) making false statements or a misrepresentation of material facts;[23] (2) conviction relating to obstruction of an investigation or audit;[24] (3) conviction relating to fraud;[25] (4) any individual the Secretary determines has engaged in fraud, provided or solicited kickbacks or engaged in other prohibited activities;[26] (5) failing to grant immediate access, upon reasonable request (a) to the secretary for reviews relating to compliance with conditions of participation or payment; (b) to the Secretary for reviews and surveys required under state plans; (c) to the inspector general for reviewing records, documents, and other data necessary to the performance of the statutory functions of the inspector general; and (d) to a state Medicaid fraud control unit;[27] (6) failure to supply payment information;[28] and (7) failure to fully and accurately disclose required information regarding ownership.[29]

CIAs are administrative settlement agreements[30] which form a contract between the entity and HHS-OIG setting forth requirements for the entity to follow to continue doing business with the government. While each CIA is tailored to address the specific facts of the case and often includes elements of a pre-existing compliance program, CIAs contain many common elements including: (1) hiring a compliance officer/appointing a compliance committee; (2) developing written standards, policies, and procedures, including a code of conduct; (3) implementing a comprehensive employee training program; (4) retaining an independent review organization (IRO) to conduct annual reviews; (5) establishing a confidential disclosure program; (6) restricting employment of ineligible persons; (7) reporting overpayments, reportable events, and ongoing investigations/legal proceedings; and (8) providing an implementation report and annual reports to the OIG on the status of the entity's compliance activities.

In addition to these common elements, the OIG has developed numerous requirements for CIAs depending on the type of provider or entity. For example, CIAs for pharmaceutical and medical device manufacturers typically include extensive requirements governing an entity's promotional functions, including the selling, detailing, marketing, advertising, promoting, or branding of products reimbursed by the government (e.g., drugs or devices); and the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, government reimbursed products, including those functions relating to any applicable review committees.

CIAs also include specific obligations regarding (1) the preparation of external dissemination of nonpromotional materials that are governed by federal requirements and distributed to HCPs; (2) contracting activities with HCPs to conduct post-marketing trials or studies related to government reimbursed products; (3) authorship, publication, and disclosure of articles or study results relating to post-marketing trials; and (4) activities related to the submission of information about government reimbursed products to compendia.

CIAs generally require entities to monitor such activities to ensure compliance with training, applicable laws and regulations, as well as the CIA itself. Most CIAs also require companies to send health care providers a letter (e.g., notice to HCPs) briefly describing the terms of the settlement between the government and the company and the alleged misconduct at issue — some also require such letters to payors. CIAs also typically require companies to track and post on company websites information about payments made by the companies to HCPs, similar to the requirements of the Physician Payments Sunshine Act.[31]

Potential False Claims Act Implications of CIA Violations

A number of recent False Claims Act complaints include allegations that entities have not only violated applicable health care laws (e.g., the AKS) or the FDCA (e.g., off-label marketing or promotion), but have also violated provisions of their CIAs. Several of these cases rely on alleged CIA violations to bolster assertions that the entity and/or its responsible executives, officers or management knew, should have known or ignored the misconduct, particularly because of CIA requirements of monitoring, training, internal reporting, and certifications.

For example, several recently unsealed qui tam complaints allege that because the company violated applicable health care and U.S. Food and Drug Administration laws and regulations, the company violated its CIA by: (1) failing to notify the OIG of reportable events; (2) failing to implement or oversee

policies and procedures regarding promotional practices and interactions with HCPs; and (3) filing knowingly false certifications that the company was in compliance with its CIA.

Allegations of FCA claims resulting from CIA violations have met with mixed success in courts. In 2012, the Eleventh Circuit ruled that a failure to comply with CIA obligations could form the basis for a FCA action. In reversing the district court's dismissal of relator's reverse false claim allegations, the court reviewed the contractual nature of the CIA, the definition of and requirement to repay overpayments within 30 days, and failure to notify the OIG of reportable events. The court focused on the allegations that the defendant falsely certified compliance with the CIA and manipulated the Independent review process to find a basis for potential FCA liability.[32]

In more recent decisions, courts have either reached different conclusions or dismissed on other grounds complaints alleging FCA violations based on claimed CIA violations. For example, one court recently held that CIAs merely impose an obligation to report, not an obligation to pay the government for CIA violations, and thus an FCA action could not be premised on alleged reverse false claims arising from claimed CIA violations.

In April 2014, the district court in Illinois examined relator's allegations that defendant Omnicare Inc. violated the False Claims Act by providing improper inducements to customers, including improper discounts for pharmaceutical services charged in a manner that allegedly violated the terms of an amended CIA. Because the court dismissed those allegations with leave to amend based on the public disclosure bar, it did not separately address the viability of the violation of the CIA theory.

Similarly, in April 2014, the court dismissed a qui tam complaint against Erlanger Medical Center based on the public disclosure bar. In a creative attempt to avoid the public disclosure bar dismissal of her earlier complaint, relator filed an amended FCA complaint alleging Erlanger's failures to report violations of unlawful activities and false certifications of compliance with the CIA were designed to cover up unlawful activities that would have led to exclusion and were in furtherance of a scheme to present false claims.[33]

In her response to the defendant's motion to dismiss the amended complaint based on the public disclosure bar, the relator argued previous public disclosures of the alleged underlying conduct did not put the government on notice of the alleged violations of the CIA. The court, however, did not find that distinction meaningful, holding that "if the government was on notice of the kinds of allegations made (in the counts relating to the underlying conduct) and it knew about the CIA (which as a party to the agreement it certainly would), the government was also on notice that Erlanger's yearly reports to the OIG might violate the CIA."

Potential OIG Response to Allegations of CIA Violations

It is unclear how the OIG will respond to relator allegations of CIA violations in FCA qui tams and subsequent court decisions or settlements. If a court finds that a manufacturer violated its CIA obligations — either by a direct finding (e.g., entity violated its CIA by not having a code of conduct) or indirect finding (e.g., promoted off-label or provided unlawful remuneration), will the OIG impose stipulated penalties? Will the OIG instead use its exclusion authority? Perhaps the OIG will impose one of the many proposals it has publicly ruminated about such as "taking away a company's patent rights as part of a settlement with the government,"[34] If the substantiated facts show widespread violations of the CIA, suggesting a culture of noncompliance, will that compel OIG to seek higher penalties?

Alternatively, if a court determines that only one employee of an entity offered unlawful inducements (e.g., isolated incident), and the entity took appropriate action (e.g., termination, retraining) and otherwise reported this information to the OIG as a reportable event or listed the incident in its annual report, the OIG may choose not to impose a penalty. Resolution of the new complaint against an entity with an existing CIA may result in an amended CIA with additional years added to the existing CIA or addition of provisions addressing the newer alleged misconduct.

Given the OIG's discretion in determining the penalties to impose, even if a court found in the context of an FCA action that an entity violated its CIA, it is unclear what action, if any, the OIG would take. OIG actions related to CIA violations likely will be determined on a case-by-case basis. While the OIG has not offered any public guidance about how it would potentially enforce CIA violations, the agency may consider the following factors (adapted from similar OIG guidance) when deciding whether to impose penalties after a court determines the CIA has been violated (either directly or indirectly):

1. What was the nature and scope of the CIA violations?

2. At what level of the entity did the CIA violation occur (e.g., sales rep or vice president)?

3. Was there evidence that the CIA violation resulted in (1) harm to patients or other individuals, and if so, to what extent; or (2) financial harm to federal health care programs, and if so, to what extent?

4. Were the CIA violations widespread and part of a pattern of wrongdoing over a significant period of time? Were the CIA violations related to the same or similar conduct, which led to the CIA?

5. What steps did the entity take to stop the underlying CIA violations or mitigate the effects of the violations? What corrective actions were taken?

6. Did the entity disclose the CIA violation to the OIG and otherwise cooperate?

7. How long had the entity been under the CIA when the violations occurred?

8. Could the entity have prevented the CIA violations?

Conclusion

The recent CSHM exclusion based on CIA violations, together with the recent FCA cases based at least in part, on allegations of CIA violations, may suggest enhanced risks for entities operating under CIAs, as well as the responsible officials and managers tasked with implementing, overseeing and certifying compliance with their respective CIAs. [35]

The factors cited by the OIG in its recent exclusion of CSHM — repeated violations and failure to maintain key policies and procedures and comply with internal compliance review requirements — should serve as a wake-up call to entities and providers operating under CIAs that the OIG will take material breaches of CIA requirements seriously. As the above cited cases demonstrate, failure to notify the OIG of reportable events, take corrective actions, monitor or oversee compliance and take compliance complaints seriously can lead to potential FCA actions, as well as OIG penalties. Allegations concerning false certifications of compliance are particularly likely to attract the attention of the OIG, relators and the DOJ.

Given this renewed focus and rare instance of imposing exclusion for CIA violations, entities currently operating under CIAs — regardless of year or stage of the CIA — should take into consideration a number of factors to ensure compliance with their ongoing CIA obligations. First, companies should ensure that internal compliance and disclosure systems are properly designed and functioning. Internal complaints — whether anonymous or not — should be handled appropriately and evaluated both for corrective action and in determining whether notification is required to the OIG. Such internal reporting is also important for creating a culture of compliance and ensuring that employee's voices are heard, rather than ignored.

Second, companies should consider reviewing and updating policies and procedures on at least an annual basis (which most CIAs already require) to determine high-risk areas. This review should also take into consideration any risk mitigation or identification programs required by the OIG or undertaken voluntarily by the company. Reviews and updates can demonstrate to the OIG not only compliance with CIA requirements, but a proactive approach to identifying challenges and new risks that may occur throughout a CIA's lifecycle, which can be expected given the ever changing nature of health care and FDA regulations, guidance and enforcement.

Third, in addition to CIA required training, companies should consider updating and retraining relevant employees to ensure that any concerns, confusion or questions about compliance are adequately addressed. While online testing and surveys, and internal compliance hotlines are one way to measure the impact of employee training and understanding of internal policies and procedures, companies also need to engage employees with interactive ways to communicate concerns that are potential CIA violations.

In fact, various manufacturers under CIAs explained that "small group training (such as that provided during in-person sales meetings) is more effective than computer-based training."[36] Training and retraining is particularly important to entities that have recently entered CIAs because initial implementation requirements are often "too short to allow for effective development of company-specific policies, procedures, and training materials."[37]

Finally, companies should revisit internal policies about the creation of documentation related to CIA requirements and obligations, as well as other compliance related matters. Given the potential for CIA documentation to be made public through FOIA requests or in parallel product liability actions, companies should consider establishing best practices for compliance related document creation to ensure that documented compliance issues or internal responses are appropriate.

Compliance officers and in-house and outside counsel must be prepared to explain and describe to government agencies how internal compliance officers identified compliance infractions or deviations and corrected such violations. As manufacturers and other health care stakeholders continue to operate in a more transparent era in the health care industry, continued oversight and compliance with applicable healthcare laws and regulations will be critical. Growing interest and investment by the government to prosecute health care fraud and abuse cases, coupled with recent allegations of noncompliance may suggest the need to revisit and revitalize the role health care compliance plays in many organizations and entities, particularly those with existing obligations to the government.

[1] Press Release, U.S. Dep't of Justice, Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Fraud (Feb. 26, 2014) available at http://www.justice.gov/opa/pr/2014/February/14-ag-206.html. This is the fifth consecutive year that the program has increased recoveries over the past year, climbing from $2 billion in FY 2008 to over $4 billion every year since FY 2011.

[2] OIG, Corporate Integrity Documents, Complete CIA List, available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.

[3] Hearing on Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges, Senate Comm. on Finance (2011) (Testimony of Daniel R. Levinson, Inspector General U.S. Dep't of Health and Human Services; Hearing on Improving Efforts to Combat Health Care Fraud, Subcomm. on Oversight of U.S. House Comm. on Ways & Means (2011) (Testimony of Lewis Morris, Chief Counsel to Inspector Gen., U.S. Dept' of Health and Human Services)(noting that the "pattern over the last 10 years doesn't indicate that forcing companies to pay money has really changed behavior").

[4] Copeland, Katrice Bridges, Enforcing Integrity (Oct. 18, 2011). Indiana Law Journal, Vol. 87, No. 3, 2011; The Pennsylvania State University Legal Studies Research Paper No. 22-2011, p.3 (noting that the use of CIAs "has not led to demonstrable reductions in health care fraud").

[5] Eric Topor, OIG Aims to Tailor Compliance Enforcement To Entities to Change Organizational Behavior, Bloomberg Health Care Fraud Report, 18 HFRA 318 (April 1, 2014) (citing Demske's comments at the Health Care Compliance Association's Compliance Institute in San Diego, California).

[6] In 2006, OIG first used its contractual authority to exclude a provider for breach of a CIA for alleged repeated and flagrant violations of its CIA, including failure to submit implementation and annual reports, failure to include required information in the reports, failure to retain an independent review organization, and failure to provide notice of its sale. The following year, OIG excluded a physician for failure to submit an annual certification and respond to OIG's stipulated penalties demand letter. See Felicia Heimer, Judy Waltz, Walking the line: When providers "go wrong" under Corporate Integrity Agreements, Compliance Today, Health Care Compliance Association, Vol. 11, No. 6 (Jun. 2009) available at http://www.foley.com/files/Publication/0bfbabbd-d4be-47df-bf69-b3236f430835/Presentation/PublicationAttachment/c51f11e8-fb54-49db-97b5-b74427c211b3/ct0609_HeimerWaltz.pdf.

[7] Press Release, OIG, OIG Excludes Pediatric Dental Management Chain From Participation in Federal Health Care Programs (Apr. 3, 2014) available at https://oig.hhs.gov/newsroom/news-releases/2014/cshm.asp.

[8] OIG, CIA Between OIG and FOBRA Holdings, LLC, available at https://oig.hhs.gov/fraud/cia/agreements/forba_holdings_llc_01152010.pdf.

[9] Supra n. 7.

[10] Id.

[11] Id.

[12] Heimer and Waltz, supra n. 6.

[13] Hersh & Hersh v. U.S. Dep't of Health & Human Servs., C 06-4234 PJH, 2008 WL 901539 (N.D. Cal. Mar. 31, 2008) (citing a declaration, ¶ 3, from the Assistant Inspector General for Legal Affairs for the OIG, Gregory Demske, who is now Chief Counsel to the OIG).

[14] Id. (citing Demske Decl., ¶ 4).

[15] Id.

[16] 42 U.S.C. § 1320a–7(c) (3) (B).

[17] Robert T. Rhoad, Brian M. Castro, Healthcare Executives in the Crosshairs: Navigating the Emerging Threat of Prosecution and Exclusion Under the Responsible Corporate Officer Doctrine, The Health Lawyer, Vol. 24, No. 5 at 5 (June 2012) (citing Robin Schneider, OIG Administrative and Civil Remedies Branch, Senior Counsel (as quoted in article, "OIG Expects to Publish by Year's End New Bulletin on Exclusions, Official Says," Bloomberg BNA Health Law Resource Center).

[18] 42 U.S.C. § 1320a–7(a) (1).

[19] 42 U.S.C. § 1320a–7(a) (2).

[20] 42 U.S.C. § 1320a–7(a) (4).

[21] Rhoad & Castro, supra note 17 at 5. OIG can exercise its discretion to impose "permissive exclusion" for a number of years, which are described in 42 U.S.C. § 1320a-7(b) (1) through (b) (16).

[22] For example, OIG issued guidance in 2010 explaining the use of its permissive exclusion authority under section 1320a-7(b) (15), which permits exclusion of any individual "who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know of the action constituting the basis for the [sanction]; or who is an officer or managing employee of such an entity." Id. [22] OIG Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b) (15) of the Social Security Act, (Oct. 20, 2010), available at https://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

[23] 42 U.S.C. § 1320a-7(b) (16).

[24] 42 U.S.C. § 1320a-7(b) (2).

[25] 42 U.S.C. § 1320a-7(b) (1).

[26] 42 U.S.C. § 1320a-7(b) (8) (as described in 1320a-7a, 1320a-7b, or 1320a-8).

[27] 42 U.S.C. § 1320a-7(b) (12).

[28] 42 U.S.C. § 1320a-7(b) (11).

[29] 42 U.S.C. § 1320a-7(b) (9).

[30] See U.S. ex rel. Wenzel v. Pfizer, Inc., 881 F. Supp. 2d 217, 220 (D. Mass. 2012).

[31] CIAs with healthcare providers such as hospitals, clinics, or individual physicians often contain different CIA obligations and requirements, such as a Claims Review, which requires the IRO to review claims submitted by the individual or entity to ensure compliance with applicable billing regulations and requirements. The OIG also enters into Quality of Care CIAs, which require a healthcare provider (e.g., hospital) to retain an independent quality monitor that not only will address the specific issues underlying the allegations, but also will look at the entity's delivery of care and evaluate the provider's ability to prevent, detect, and respond to patient care problems.

[32] U.S. ex rel. Matheny v. Medco Health Solutions Inc., 671 F.3d 1217 (11th Cir. 2012).

[33] United States of America ex rel. Lisa K. Stratienko v. Erlanger Med. Ctr., No. 1:10-cv-322, Memorandum (E.D. Tenn.) (Mar. 28, 2014)

[34] Kelly Kennedy, Experts seek alternatives to excluding drug companies, USA Today (March 5, 2012) available at http://usatoday30.usatoday.com/news/washington/story/2012-03-05/penalties-drug-companies/53372918/1(noting that OIG was "considering taking away a company's patent rights as part of a settlement with the government").

[35] It is unclear whether government or relator allegations and/or subsequent settlements and court findings could result in Park Doctrine prosecutions of officials responsible for submitting CIA certifications (and related corporate officer certifications to DOJ). Under the Park Doctrine, a corporate official may be convicted of a misdemeanor violation of the FDCA without personally engaging in wrongdoing, or even knowing about another person's violation of the statute, provided the official had the responsibility or authority to prevent or correct the FDCA violation but failed to do so. Many CIAs contain provisions that require the entity to comply with FDCA provisions that require full compliance with FDA regulations regarding adverse event reporting, scientific exchange, and all forms of promotional activities (e.g., journal and compendia submissions, exhibits, etc.).

[36] OIG, Report From February 23, 2012, Pharmaceutical Compliance Roundtable, p. 2 available at https://oig.hhs.gov/compliance/compliance-guidance/docs/Pharmaceutical-Compliance-Roundtable.pdf.

[37] Id.

Marilyn May is a counsel in Arnold & Porter's Washington, D.C., office and former head of health care fraud enforcement for the U.S. Attorney's Office in the Eastern District of Pennsylvania.

Abraham Gitterman is an associate in Arnold & Porter's Washington office. Gitterman is admitted only in Pennsylvania and New Jersey and is practicing law in the District of Columbia during the pendency of his application for admission to the D.C. bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. bar