Cooley

HEALTH CARE/LIFE SCIENCES REGULATORY

Key Considerations for Government Health Care Fraud Investigations/Inquiries

PREPARING FOR A GOVERNMENT INVESTIGATION/INQUIRY

In today's government enforcement environment, it is critical for health care and life sciences companies to take certain steps to prepare the organization and its employees for a government investigation/inquiry before one occurs. Key considerations include:

- ☐ **GOVERNMENT KNOCK POLICY.** Companies must develop, implement and train employees on a policy regarding contacts from a government enforcement agency. The policy should address all types of potential contact, including company service of process and raids. It also should provide employees with information regarding their obligations and rights if they are contacted directly by government agents.
- ☐ **CORPORATE COMPLIANCE.** It is critical for companies to implement an effective corporate compliance program that prevents, detects and fixes potential issues before they result in a government action. This includes robust internal investigation processes. *See* **20 Key Considerations For Implementing An Effective Corporate Compliance Program.**
- ☐ **ELECTRONIC SYSTEMS INVENTORY.** Many health care and life sciences companies have a significant number of current and historic electronic systems that contain company data and information that may be critical to a government investigation/inquiry. Companies should maintain a list of all active and retired systems, including business owner, purpose, vendor, dates of use, and data size.
- ☐ **IT SYSTEM MANAGEMENT.** The IT group of health care and life sciences companies must create, maintain and retain critical information related to the company's IT infrastructure, including hardware, software and cloud systems. This must include documented policies and procedures related to the creation, retention, destruction and re-use of disaster recovery systems.
- ☐ **RECORDS MANAGEMENT.** Companies must implement a written records management program and ensure rigorous adherence to these records management policies and processes.
- ☐ **COUNSEL LIST.** Companies must maintain a list of all internal and external counsel of the company, including relevant areas of law or specific responsibilities, any special or significant legal projects, and dates of service.
- ☐ **INVESTIGATION TEAM.** Companies should become familiar with external counsel experienced in handling health care fraud investigations/inquiries. Companies also should become familiar with public relations and crisis management firms that specialize in "bet the ranch" litigation for health care and life sciences companies. Keep contact information available.

RESPONDING TO A GOVERNMENT INVESTIGATION/INQUIRY

Government investigations/inquiries of any type or size are a distraction from the company's mission and strain company employees and resources. When a health care or life sciences company becomes aware of a government investigation/inquiry, it must be prepared to respond effectively and efficiently. It also must understand that some investigations/inquiries may take several years to fully resolve. Understanding the government investigation/inquiry process and time lines is critical. Key considerations include:

- ☐ **INITIAL ASSESSMENT.** If a subpoena duces tecum or civil investigative demand (CID) was received by the company, was it issued under civil, criminal and/or administrative authority? What statutes are cited? What insight can the document requests provide regarding the potential nature of the matter?
- ☐ **ASSEMBLE THE TEAM.** Will the company engage outside counsel experienced in handling health care fraud

investigations/inquiries? What other subject matter experts are needed? Does securities counsel need to be made aware of the matter? Will the company engage a third party litigation support vendor to assist with document collection, processing and/or production? What internal resources will be dedicated to this matter?

- ☐ **BOARD EDUCATION.** Does the Board of Directors need to be educated on the health care fraud investigation/inquiry process? Who will provide this education?
- ☐ **CASE POSTURE.** Will the company challenge the matter in court? Is the company dedicated to full cooperation with government investigators, including timely disclosure of information?
- ☐ **DOCUMENT HOLD NOTICE.** Which employees, vendors and/or agents need to receive the document hold notice? What message(s) do we want to convey though this notice?
- ☐ **COMPANY STATUS.** Is the investigation/inquiry civil and/or criminal in nature? Is the company a target, subject or witness of the investigation/inquiry? Does the matter involve a qui tam relator? What agencies are involved in the investigation/inquiry?
- ☐ **PRIORITIZATION.** Are there specific documents requests, products/services, and/or time periods that are of particular importance? Are there specific document populations that should be prioritized? Will the government allow rolling productions?
- ☐ **ESI STRATEGY.** In which systems is the potentially responsive electronically stored information (ESI) located? What must the company do to appropriately preserve and/or collect this ESI? Which e-discovery tools will be used to assist with the identification, review and production of ESI? What are the government's electronic production specifications, including deduplication requirements?
- ☐ **DOCUMENT COLLECTION.** Which individuals, departments and/or systems likely contain the most significant potentially responsive documents? Does the company have any specific document collection challenges, such as field employees, mobile devices or cloud systems?
- ☐ **DOCUMENT REVIEW STRATEGIES.** Will search terms be used? Will the company review all or a subset of potentially responsive documents? Will the review be conducted proactively or reactively? Will documents be reviewed by outside counsel, contract attorneys, predictive coding, or other means?
- ☐ **PRIVILEGE.** Which document populations may contain potentially privileged information, patient health information and/or other protected personal information? Will a special process for reviewing and producing these document populations be used? Are there any committees that included a legal representative for which a privilege analysis needs to be conducted? Will government investigators permit a clawback agreement?
- ☐ **INTERNAL INVESTIGATION.** Is it the appropriate time to conduct an internal investigation based on what the company knows about the government investigation/inquiry? Who will conduct the internal investigation? Will the internal investigation be conducted under an applicable legal privilege? Are there any conflicts of interest that need to be addressed?
- ☐ **COMPANY EMPLOYEES.** Are company employees being targeted by the government? What type of employee interview is being requested – "formal", such as a deposition or grand jury, or an "informal" discussion with government investigators? Does the employee need or want his/her own counsel? Will the company provide individual counsel to the employee? Does the company need or want a joint defense agreement with the employee?
- ☐ **GLOBAL RESOLUTION.** Are all existing civil and criminal matters under investigation being resolved, including all qui tam cases filed under the False Claims Act (FCA)? Are all investigating agencies involved in the settlement? Is the government seeking debarment, exclusion and/or integrity obligations? What is the company structure and is it prepared for debarment or exclusion? What other administrative or collateral consequences need to be addressed as part of the global resolution? How will the company handle resolution of any other qui tam relator claims under the FCA (or similar state statutes), such as retaliation and attorney's fees, expenses and costs?
- ☐ **CIA READINESS.** What must the company do to prepare for a corporate integrity agreement (CIA) and/or other post-settlement compliance or integrity obligations? Which potential independent review organizations (IRO) will the company consider based on independence criteria? Are there other entities in the corporate family that ultimately may be subject to the CIA?