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Planning for Increased Health-Related Enforcement Efforts in 2022: Responding to Government Audits and Investigations

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The Department of Justice (DOJ) has made numerous recent public statements reflecting increased priorities for enforcement, especially in the health care industry. The DOJ has a variety of tools at its disposal to enforce civil and criminal laws and has several methods of obtaining information during health care fraud and abuse investigations. Precious time will be lost, and important steps will be inadvertently missed, if an organization waits until an investigation is underway to decide how it and its employees should react to a government inquiry for information. Developing a well-thought-out policy for responding to government investigations requires understanding:

1. The potential legal liability the organization may be facing,
2. The type of inquiry method the government is using, and
3. The appropriate role legal counsel can play during the investigation.

Entities and individuals should take the opportunity now to review their own procedures for responding to the government. Understanding the requests and some essential best practices will help prepare for inquiries that are becoming a regular part of operations.

Understanding Common Legal Bases for Investigating Potential Liability

The DOJ has at its fingertips very powerful tools for protecting government funds against fraud and abuse. In addition to federal laws, each state may have enacted its own laws which are designed to mirror their federal counterparts. This section will focus on the federal laws the government most often relies upon in health care fraud and abuse cases.

False Claims Act

The government's main tool of civil enforcement is the False Claims Act (FCA). The DOJ recovered $2.2 billion in settlements and judgments in FY 2020 with $1.8 billion of those dollars involving the health care industry. All signs point to 2022 being another year of significant FCA settlements and judgments in the health care industry. The ever-expanding reach of the FCA continued through 2021 with the DOJ announcing the Civil Cyber-Fraud Initiative and the formation of a COVID-19 Fraud Enforcement Task.

The FCA provides a remedy of civil damages when a party makes a false statement or engages in a fraudulent course of conduct that is done with scienter that was material and caused the government to pay out money or forfeit money it was due. The FCA is unique in that it allows a relator (a/k/a whistleblower) to bring a civil claim called a qui tam claim as a partial assignee for the government. The relator effectively acts as a private attorney general. The FCA provides that the qui tam relator can stand to recover for themselves anywhere from 15 to 30 percent of the damages and penalties or settlement that stems from the claim.

The FCA provides for damages which are three times the actual damages for each claim submitted on top of penalties per claim ranging from $11,803 to $23,607. In the health care arena, each discrete procedure code reimbursed by the government is considered a claim for the purposes of evaluating damages under the FCA. Thus, successful FCA actions are almost always extremely costly for the health care provider.

Anti-Kickback and the Health Care Fraud Statute

The Anti-Kickback Statute (AKS) is a federal criminal statute that prohibits any person from "knowingly and willfully" offering, paying, soliciting or receiving remuneration to induce or reward referrals (or in exchange for referrals) in order to generate federal health care program business. Remuneration is anything of value (e.g., joint venture proceeds, entertainment, meals, educational and research funding, free or below fair market value goods, or rebates). A claim paid out in violation of the AKS can also be false, which triggers FCA liability. The AKS is different from the physician self-referral (Stark) law because AKS, unlike the Stark law, is not limited to the referral of ***designated health services*** by a ***physician***. Additionally, unlike Stark, the AKS is an intent-based statute, meaning the government must prove intent to induce the referrals.

The general Health Care Fraud Statute is a key tool used by the DOJ in health care fraud enforcement actions. The statute applies to health care benefit programs; therefore, it can be applied to federal and private health care payers. It makes it illegal to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud any health care benefit program.

In its May 2021 National COVID-19 Health Care Fraud Takedown, the DOJ announced criminal charges against 14 defendants across seven federal districts for their participation in health care fraud schemes related to the COVID-19 pandemic which resulted in $143 million in alleged false billings. In late 2021, the DOJ charged 138 defendants, including doctors, nurses, and other licensed medical professionals, for their alleged participation in various fraud schemes that resulted in an alleged loss of $1.4 billion. Among the fraud schemes involved were telehealth fraud and COVID-19 health care fraud. These types of interagency coordinated efforts to identify and prosecute health care fraud are likely to continue in 2022.

Types of Inquiries

Generally, the types of inquiries can be categorized by the level of control the government maintains over the response to the inquiry, reflecting various factors that may impact the information's role to potential government action. For purposes of this discussion, the categories of requests are divided into three groups: Group 1, Group 2, and Group 3.

The government may have one of several different motives for obtaining information. It may be doing so to exercise its general oversight and inspection role to maintain the health, safety and welfare in the delivery of health care. It may be doing so in response to a complaint from an individual or another regulatory body about possible civil or criminal fraudulent behavior. Lastly, an inquiry might be made for the purpose of health care policy development.

When a health care organization is developing its response policy, it needs to include specific affirmative steps an organization or employee of the organization should take in response to one of these inquiries. The higher the level of concern, the more formal the policy should be, and the sooner legal counsel should become involved.

Group 1

Requests for Voluntary Cooperation/Letter Requests: Federal and state agencies are using an informal type of inquiry that allows for a broader scope than would be allowed by formal inquiries which are authorized by law. An agency will ask for voluntary cooperation in providing certain types of information and documents.

This trend is troubling because most government inquiries are limited in scope; however, when an organization voluntarily produces information pursuant to an informal request, there are no scope restrictions.

Licensing Agency Audit/Inspection: Pursuant to regulations or statutes within a state, an organization may be subject to periodic audits or inspections which could include an on-site visit or a request for documents.

Administrative Subpoena: Federal agency requests most frequently come from the Office of Inspector General (OIG). These subpoenas may be used in both criminal and civil investigations and are often issued in consultation with an Assistant United States Attorney.

Group 2

Civil Investigative Demand (CIDs): The government derives its power to issue CIDs through the FCA. In recent years, it has increasingly used CIDs to gain information because they are fairly broad in nature and do not require the government to justify the request to the judiciary as is required with a search warrant. What makes these requests different from those in Group 1 is that they can compel not only document production, but also answers to questions in the form of interrogatories and can compel individuals or organizations to give answers under oath at a deposition.

- The FCA specifies procedures for responding to a CID. The rules for responding to interrogatories and participating in a deposition differ in this context than in traditional discovery under the Federal Rules of Civil Procedure.

- CIDs are used by the government to investigate qui tam lawsuits that remain under seal, which may limit a company's ability to comprehend the complete extent of the government's investigation while it is responding to a CID.

- The government has broad authority under the FCA to utilize CIDs to obtain a wide array of information that may be relevant to its investigation. The information can be shared with states, criminal prosecutors, and even third parties.

Group 3

Grand Jury Subpoena: Grand jury subpoenas are issued by a grand jury and can only be used as part of ***criminal investigations***. Grand jury subpoenas can only be issued with the assistance of a prosecutor.

HIPAA Subpoena: A HIPAA subpoena is another form of administrative subpoena used by the DOJ pursuant to 18 USC 3486, but is unique in that it is only available when there is an open ***criminal investigation.***

Search Warrant: Search warrants are issued by federal magistrates and are only available in ***criminal investigations***. A search warrant must be supported by a showing of information sufficient to establish probable cause of criminal activity. The information necessary to establish probable cause is usually present in the form of an affidavit submitted to the magistrate with the request to issue a search warrant. A search warrant gives the government the right to enter the property described in the warrant and seize items listed with particularity in the warrant. The officers executing the warrant must complete an inventory of property seized and leave a receipt for the items.

Civil Investigation Demands, Subpoenas, and Surveys

For most cases, the government submits requests to an organization and the organization is responsible for collecting and providing information. In these situations, there are several important steps that should be followed in virtually every instance. It is advised that outside legal counsel is contacted because each step

requires unique knowledge of government investigations.

Steps for Collecting and Providing Information in Response to a Government Request

Preservation	Determine the scope of preservation necessary and the required notices that need to be sent.
Assessment	Evaluate the time and expense of production, difficulty of retrieving data, whether documents have been destroyed, and the likely focus of the investigation.
Negotiation	Continue an on-going dialogue with government counsel to arrive at a successful result.
Collection	Collect information under the direction of legal counsel during the course of an internal investigation.
Review	Conduct a careful review of the collected documents with legal counsel to determine their responsive nature.
Production	Produce documents promptly and maintain a positive relationship with the government.
Re-Negotiation	Continue to keep government counsel informed of progress and scheduling.
Parallel Internal Investigation	Assess any risks or issues identified while production is on-going.

Search Warrants or Inspections

A search warrant or inspection is the fastest way for the government to get information, but the information obtained is unorganized and is not necessarily focused on the questions the government is seeking to answer. An organization's policy and procedures should set out each step to be taken during and after a search. The moment the government shows up with a warrant is not the moment employees should be trying to figure out who should be notified and what else needs to be done. A good internal procedure will be developed in advance, with the assistance of counsel, and will address:

- Immediate actions to be taken when the search warrant is served;
- Conduct of employees, counsel, and management while the search warrant is being executed; and
- Actions to be taken after the government has completed its search and any seizure.

A comprehensive policy will also address important general concepts including required notifications, the rights of individual employees and the organization, requests or attempts to interview employees during the execution of the warrant, the importance of cooperation and preservation of evidence, the fact that under no circumstances should anyone interfere or obstruct access to records pursuant to a valid search warrant, and how to respond when some seized documents may be privileged. These issues and this process should all be developed with the assistance of counsel.

After a search is conducted, outside counsel can contact law enforcement agents to gain additional information about the search and any related investigation. That fact that a search warrant was issued is a good indicator that an internal investigation under direction of counsel is likely in the best interest of the organization.

Final Thoughts

One investigation can trigger inquiries by multiple regulatory agencies, and government investigations also can involve multiple federal and/or state regulatory bodies. Since each agency may issue its own request for information, organizations should be prepared to respond to multiple simultaneous requests.

It is also imperative to keep in mind that an investigation may initially involve only one agency, but that agency may share information with other federal and/or state agencies, leading to a "domino effect" where other agencies initiate their own investigations. This domino effect emphasizes the importance of consulting with counsel before responding to the first inquiry as opposed to waiting to bring counsel in latter in the investigation.

If your organization does not have a policy for responding to government investigations (search warrants, subpoenas, document demands and interview requests), now is the time to get to work. The new year is the perfect time to improve organizational policies and procedures. A well-thought-out plan developed in conjunction with legal counsel can minimize an organization's potential risk during a government investigation.

For more information contact Thomas Barnard or your Baker Donelson Health Law attorney.