M. The Nuts and Bolts of a Health Care Fraud Investigation/Resolution

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Sources of Cases

We’ve all seen the statistics from the Department of Justice showing the huge increase in the number of health care fraud cases and recoveries over the past 10 years. Here is a link to a chart showing the latest numbers through September 2013: http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

As you can see, the number of *qui tam* matters\(^1\) has increased at an enormous rate, particularly in comparison with the number of non-*qui tam* matters. For example, in 2003 there were only 334 *qui tam* cases filed; 10 years later that number had grown exponentially to 846 new *qui tam* cases. By contrast, there were 92 non-*qui tam* cases in 2003; 10 years later in 2013 that number was almost the same, 93.

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\(^1\) The False Claims Act, 31 U.S.C. § 3729 et seq., includes a “*qui tam*” provision (from a Latin phrase meaning “he who brings a case on behalf of our lord the King, as well as for himself”), which permits a private person – also known as a whistleblower or a relator – to file a suit under seal on behalf of the United States where the defendant is believed to have knowingly submitted or caused the submission of false or fraudulent claims to the United States. The complaint, and all other filings in the case, remain under seal for a period of at least 60 days. For an overview of litigation under the False Claims Act, see http://www.justice.gov/usao/pae/Civil_Division/InternetWhistleblower%20update.pdf.
According to Assistant Attorney General Stuart Delery, 80% of the *qui tam* cases are declined.\(^2\) Interestingly, and as reflected in the chart referenced above, of the almost $3 billion recovered in settlements and judgments in *qui tam* cases in 2013, only $109 million (or slightly less than 4%) was recovered in cases where the government declined to intervene.

*Whistleblowers*

Who are the whistleblowers? The whistleblower community comprises a broad spectrum of professions and roles – from an FDA reviewer in a recently unsealed case, to compliance officers, to doctors who received sales calls, to sales representatives for pharmaceutical or medical device companies, to industry competitors – pretty much everyone and anyone can be a whistleblower. And much to the chagrin of the Department of Justice, even federal employees are included in the group. A whistleblower can even be someone who participated in the fraud, as long as that person was not convicted.

*Other Sources*

Whistleblowers are not the only source for health care fraud cases. Some cases start with referrals from agencies or their contractors (*e.g.*, FDA, HHS-OIG, FBI, Zone Program Integrity Contractors (“ZPICs”)), which receive tips and leads from a wide variety of sources, including personal injury attorneys, patients, Medicare Fraud patrols, state Medicaid Fraud Control Units (“MFCUs”), or competitors. Other cases are

\(^2\) “For every ten cases filed by relators, the government ultimately intervenes in only two.” [http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html](http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html)
generated by law enforcement teams (prosecutors and agents) which scour data, industry information, and news articles for potential matters to pursue.

**Who’s Who in a Health Care Fraud Investigation?**

Health care fraud investigations typically involve lots of players and a virtual alphabet soup of agencies. Let’s start with the attorneys. If there is a criminal case, there is usually an assigned Assistant United States Attorney (“AUSA”) from one or more of the 93 U.S. Attorney’s Offices throughout the United States, Puerto Rico, the Virgin Islands, Guam, and the Northern Mariana Islands. In matters involving the Food, Drug and Cosmetic Act, there may also be an attorney from the Consumer Protection Branch in Washington, DC, (which is tasked with representing the FDA in both criminal and civil actions under the Food, Drug and Cosmetic Act). If your district also has a Medicare Strike Force (known as “HEAT” for Health Care Fraud Enforcement and Prevention Team), there may also be criminal attorneys from the Department of Justice in Washington, DC, (often referred to as “Main Justice”) involved in the investigation. Civil investigations often involve a civil AUSA from one of the 94 U.S. Attorney’s Offices, and they may also involve an attorney from the Civil Fraud section of Main

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3 http://www.justice.gov/civil/cpb/cpb_practareas.html

4 The joint DOJ-HHS Medicare Fraud Strike Force is a multi-agency team of federal, state, and local investigators who work together to fight Medicare fraud. The Strike Force uses Medicare data analysis techniques and an increased focus on community policing to combat fraud. The Medicare Fraud Strike Force has recently expanded to include nine cities: Baton Rouge, Louisiana; Brooklyn, New York; Chicago, Illinois; Dallas, Texas; Detroit, Michigan; Houston, Texas; Los Angeles, California; Miami–Dade, Florida; and Tampa Bay, Florida. http://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/
Justice if the matter has potential damages over $1 million. Depending on the matter, either or both the AUSA and the Civil Fraud attorney will be running the civil investigation. There may also be agency attorneys involved, most commonly an attorney from the FDA or HHS-OIG. Depending on the issues in the case, an attorney from the Centers for Medicare and Medicaid Services (“CMS”) may also be involved.

If the civil investigation involves potential Medicaid claims, there may also be an attorney from the local state attorney general’s office of the MFCU. If the case involves potential nationwide Medicaid claims, there may be attorneys or a committee from the National Medicaid Fraud Control Units (“NAMFCU”).

Health care fraud investigations often involve agents from many different agencies, as well as various consultants, data crunchers, and other experts. The agents may come from agencies that have potential damages to their programs, including not only the usual suspects such as the FDA and HHS, but also the Department of Defense, Veteran’s Administration, Office of Personnel Management (which investigates, among other things, frauds directed at the Federal Employees Health Benefits Program, which is the world’s largest employer-sponsored group health insurance program and insures approximately 8 million people), and the Department of Labor (which administers various federal workers’ compensation programs). For Medicaid, which is jointly funded by the federal government and the states, there may also be state agents from the state MFCU or state attorney general’s office who may assist in an investigation. In addition to providing agents to assist with the investigation by interviewing witnesses, reviewing documents, and gathering information, the various agencies also provide information
about their programs, damages, potential loss (for criminal cases), and claims information.

If there is a whistleblower or relator, and depending on that person’s experience, the type of case, and the willingness of the Department of Justice attorneys to let the relator and the relator’s counsel be involved, the relator may provide assistance from the beginning, including making suggestions for documents to be requested by subpoena, witnesses to be interviewed, or expert opinions to be sought, and even sometimes assisting in the review of subpoenaed materials (documents and data). Relators do not have a prescribed role, or any specified level of involvement, in _qui tam_ cases. Some Department of Justice attorneys depend on relators and their counsel to assist in steering through the investigation, while others are more reluctant to turn over or share the reins of the investigation with relators and their counsel. Some Department of Justice attorneys are cautious about relying on relators’ information, knowing that it is potentially biased due to the relators’ personal financial stake and that such potential bias might not only skew the investigative process, but also will be an easy basis for cross-examination if the case were to proceed to trial.

Although you might assume there is a judge overseeing the government’s investigation, in most instances that assumption is incorrect. In the grand jury setting, while there is a grand jury judge assigned to supervise all matters occurring before a particular grand jury, the grand jury judge typically plays no active role in the actual

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5 A federal grand jury generally is empanelled to hear testimony one day a week for 18 months, although this can be extended to 24 months.
conduct of the investigation, except for the rare circumstance when a motion is filed by the prosecutor or defense counsel (for a witness or the subject or target\textsuperscript{6} of the investigation) prior to the return of an indictment.

In a criminal investigation that does not yet involve the grand jury, there is no judicial supervising role, except for the magistrate judge who may have approved an application for a search warrant if the prosecutor demonstrates that there is probable cause to believe that a crime has been committed and that evidence or contraband of that crime is located at the place to be searched.

In a civil investigation that does not involve a \textit{qui tam}, there is no judicial involvement whatsoever in the investigation. If there is a filed \textit{qui tam} complaint, there will be a judge assigned to the case, but the role of the judge will vary depending on the judge. Typically, an assigned judge will be concerned with the progress of the investigation as it relates to the government’s requests for extensions of the seal for good cause. Although the False Claims Act requires cases to be filed under seal and for the United States to decide whether to intervene in the case within 60 days unless good cause exists for an extension, the government almost always files requests to extend the time period to make that intervention determination, as well as to extend the seal, often extending both for years. These requests for extensions are themselves filed under seal.

\textsuperscript{6} The United States Attorneys’ Manual defines the “subject” of an investigation as “a person whose conduct is within the scope of the grand jury’s investigation.” A “target” is defined as “a person as to whom the prosecutor or the grand jury has substantial evidence linking him or her to the commission of a crime and who, in the judgment of the prosecutor, is a putative defendant.”

Before granting extensions, some judges require a detailed explanation from the
government of what steps it has taken so far, as well as what additional steps it plans to
take and the time required to do so; however, other judges may be satisfied with a more
barebones recital of the reasons for requesting extensions. While there has been some
discussion in the defense bar that the court should play a greater role in investigations, so
far that has not been the case, and the court’s role typically has been *de minimis*.

**Initial Stage of an Investigation**

*Notification of Investigation*

If you work for a corporation, you may learn about the existence of a government
investigation when you receive a panicked call from an employee reporting that the FBI
is at her house to talk to her. Or perhaps one of the first employees to arrive at the office
calls in a tizzy to report that federal agents are at the door with a warrant. Or maybe
instead of an agent at the door, you get a call from an AUSA, who is asking questions and
seeking information about a matter under investigation.

Although you may just be finding out about an investigation, the reality is that the
investigation may have been proceeding for a long period of time before you find out
about it. And lots of evidence may have been collected by the time you learn about the
investigation. Among other things, a whistleblower may have taped meetings and other
conversations, downloaded hundreds of documents to provide to the government, and
given the government a road map as to what the whistleblower perceives to be fraud.
There may be a case that was filed under seal months or years earlier that you know nothing about.⁷

How you learn about the investigation may tell you something about the type of investigation. If a search warrant is executed, then there is a criminal investigation. To obtain a search warrant, the government had to convince a magistrate judge there was probable cause to believe a crime has been committed and that evidence or contraband of that crime is located at the place to be searched. Any information obtained during a search can be shared with the civil AUSAs and agents working on a case. The issuance of a grand jury subpoena to your company or its current or former employees/customers/contractors also signals a criminal investigation. Grand jury subpoenas are issued only in connection with criminal investigations. While there may also be a parallel civil investigation, the information obtained by way of a grand jury subpoena cannot be shared with civil AUSAs.

*Is It a Criminal and/or Civil Investigation?*

Although the Department of Justice has long had a parallel proceeding policy⁸, the current administration has placed increased emphasis on coordination of criminal and civil investigations. A memorandum issued by Attorney General Eric Holder in 2012

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⁷ The government may also proceed by a number of covert means, which may be undertaken both before you are aware of the investigation and while an overt investigation is proceeding. For example, the government may tape witnesses (either consensually or through court-approved wiretaps), use mail covers (tracking information on mail received/sent), pen registers (tracking calls made and received), or conduct trash or garbage runs to obtain information.

requires that information be shared between criminal and civil AUSAs to the fullest extent appropriate to the case and permissible by law. As you can see from the below excerpt of current Department of Justice policy, there is a focus on coordination and sharing of information between criminal and civil AUSAs from the very beginning of the case:

- **Intake:** From the moment of case intake, attorneys should consider and communicate regarding potential civil, administrative, regulatory, and criminal remedies, and explore those remedies with the investigative agents and other government personnel;
- **Investigation:** During the investigation, attorneys should consider investigative strategies that maximize the government’s ability to share information among criminal, civil, and agency administrative teams to the fullest extent appropriate to the case and permissible by law, including the use of investigative means other than grand jury subpoenas for documents or witness testimony; and
- **Resolution:** At every point between case intake and final resolution (e.g., declination, indictment, settlement, plea, and sentencing), attorneys should assess the potential impact of such actions on criminal, civil, regulatory, and administrative proceedings to the extent appropriate.

One of the ways you may determine that there is a parallel civil/criminal investigation is if you receive a HIPAA subpoena, also known as an Authorized Investigative Demand. Unlike grand jury subpoenas (which are subject to grand jury

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10 A HIPAA subpoena has nothing to do with privacy of medical records and the types of matters that are commonly thought of as HIPAA matters. The 1996 Health Insurance Portability and Accountability Act (“HIPAA”) also provided for authorized investigative demands, commonly referred to as HIPAA subpoenas, which allow a criminal AUSA to issue a request for documents related to any health care fraud violation. The U.S. Attorneys’ Manual describes HIPAA subpoenas as follows: “On August 21, 1996, the President signed into law the Health Insurance Portability & Accountability Act, P.L. 104-191. Section 248 of P.L. 104-191 adds a new statute, 18 U.S.C. § 3486. This provision empowers the Attorney General, or the Attorney General’s designee, to issue

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secrecy rules imposed on the government under Federal Rule of Criminal Procedure 6(e)), documents and evidence obtained by the criminal AUSA’s issuance of a HIPAA subpoena can be shared with the AUSA’s civil counterpart. Civil AUSAs, however, cannot issue HIPAA subpoenas; so if you receive a HIPAA subpoena you can be sure there is a criminal investigation underway and can probably safely assume there is also a civil investigation.

Civil AUSAs, meanwhile, can and are increasingly using Civil Investigative Demands (otherwise called CIDs) to obtain testimony, documents, answers to interrogatories, or any combination of the above. According to a 2012 speech by Assistant Attorney General Stuart Delery, “In the last fiscal year, the Department authorized the issuance of 888 CIDs – more than 10 times the number of CIDs issued during the two years before re-delegation combined.”

If the investigation includes potential damages in excess of a million dollars, approval for any CID must come from the Department of Justice in Washington, DC; otherwise, a CID can be approved by the local U.S. Attorney.

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investigative demands to obtain records for investigations relating to Federal criminal health care fraud offenses; these records are not subject to the constraints applicable to grand jury matters set forth in Fed. R. Crim. P. 6(e).”

11 See http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html. Prior to March 24, 2010, only the Attorney General could authorize issuance of a CID. On that date, however, the Department of Justice expanded the ability to issue a CID under the False Claims Act by delegating that authority to all 93 U.S. Attorneys, as well as the Assistant Attorney General for the Civil Division.
Civil AUSAs may also rely on agency Inspector General subpoenas to obtain documents. To obtain such subpoenas, the agent from an agency that has Inspector General authority (such as HHS-OIG) often has to obtain approval from its agency headquarters and its attorneys.

Beyond formal investigative tools, both criminal and civil AUSAs may send a letter or informal request for information, including documents. Criminal and civil AUSAs may also conduct informal interviews of employees/former employees/customers and others to obtain information that may be shared with their counterparts in the other division. Criminal AUSAs (and sometimes civil AUSAs) may interview witnesses in what are referred to as proffer sessions, in which the AUSAs agree to interview the witness under certain conditions, such as agreeing not to use anything the witness says in the interview against the witness in the government’s case-in-chief, but permitting such statements to be used on cross-examination if the witness testifies to the contrary, as well as permitting the government to make derivative use of the information provided by the witness.12

With the Department of Justice’s emphasis on parallel proceedings, you may see the investigation being conducted by both criminal and civil AUSAs and agents (and sometimes even one AUSA wearing more than one hat, such as a civil AUSA who is cross-designated to also serve as a criminal AUSA for a particular case or group of

cases). As a practical matter, this means the criminal and civil AUSAs involved may have a joint investigative plan, the civil AUSA may have drafted the language identifying the materials (documents and data) requested in the HIPAA subpoena, the criminal AUSA may be attending or at least reading the transcripts of CID testimony, and both the criminal and civil AUSAs will attend witness interviews/proffers sessions, as well as review materials collected.

The civil AUSA will often try to have the criminal AUSA hold off on convening a grand jury investigation for as long as possible so that the civil AUSA will continue to have access to materials and interviews. Once a grand jury investigation has been opened, the AUSAs will frequently erect a wall between the criminal and the civil investigations to avoid any potential allegations of breach of grand jury secrecy. The interpretation of “matters occurring before the grand jury,” however, varies by jurisdiction and by U.S. Attorney’s Office. For example, some Offices will not consider business documents already in existence obtained by way of a grand jury subpoena as matters occurring before the grand jury and, accordingly, will allow those documents to be shared with civil AUSAs. Other Offices take a more conservative approach and will not share those documents with the civil AUSAs. To avoid potential inadvertent sharing of grand jury information, some Offices will also have separate agents assigned to the criminal and civil cases.

*Initial Response*

The nature of the investigation, as well as the manner in which it is brought to your attention, will dictate your initial response. For the rare scenario involving a search
warrant as part of a criminal investigation, it is important to have a plan in place in advance and, equally as important, all of your employees should be aware of that plan. This includes making sure that employees know to contact counsel or a designated point-person immediately when the agents arrive. Companies often routinely send all nonessential personnel home; this helps limit the number of employees present who may be interviewed by agents and, in the process, may provide the agents with information and/or consent to expand the scope of the search. While no employer should ever instruct its employees not to speak with agents or law enforcement, it is permissible for employers to let employees know their rights, including that they have the right to refuse to answer questions, as well as that they can choose to have counsel present if they agree to speak with the agents. Often searches are conducted with the dual purpose of obtaining documents and evidence and conducting interviews of employees without counsel present.

In addition to having a plan if a search warrant is executed, employers should also have a plan in place and should train employees on what to do (including obtaining the name, title, and agency for all agents present) and who to contact if one or more federal agents want to interview them. Agents (often carrying weapons), frequently show up at employees’ homes early in the morning or later in the evening, where they can catch the employees unaware, before the employees have a chance to consult with counsel. Because the employees are not considered to be in custody, the agents do not have to provide them the well-known Miranda warnings. Employees should be trained in advance so that they will not panic and will understand they can choose whether to talk to
the agents and whether to do so with counsel (either of their own choosing or company counsel) present. While it is important to make clear that employees can decide whether to go forward with an interview, they should also understand that if they choose to do so, the company expects and requires that they provide completely truthful and accurate information.

In order to respond effectively to the government, you will have to understand the underlying facts as well as the potential issues. If you have received any type of subpoena, the subpoena itself should help you understand the issue or issues being investigated. For example, if the materials requested relate to marketing or promotion of your product and/or the witnesses subpoenaed to testify work in your marketing department, those pieces of information give you some sense as to where you should focus your efforts to better understand the issues that may be under investigation. The questions of whether to conduct an internal investigation, the scope of the investigation, who should conduct the investigation, who will supervise it, whether it will be conducted under privilege (even if waived later), and what you anticipate doing with the results of the investigation are all decisions to make at the outset. The answers may depend in part on the issues, what’s at stake, and the costs of conducting an investigation.

As the investigation will likely include requests by the government for production of materials, it is important to preserve all potentially relevant evidence and to issue a document hold notice as quickly as possible. The hold notice should be in layman’s terms and distributed to all persons who likely possess or have access to relevant materials, and it should include a list of materials to be retained, as well as instructions on
how the materials will be collected. Given the many ways in which employees communicate, store, and delete information, it will be important to take steps to retain, review, and produce responsive, non-privileged information. Consider the ways in which employees communicate, such as text and instant messages, and include them in your document hold request. Many companies now have what is commonly referred to as a “bring your own device” policy. Make sure you have company policies that cover access to the potential business information contained on employees’ personal phones, tablets, computers, etc.

The Investigation

Gathering the Information and Responding

Right from the very beginning, it is important for counsel to set the appropriate tone for interactions with the government. While your first instinct may be to fight with the government, sometimes working cooperatively can be more effective in the long run. You should always remember that you are invariably starting out playing catch-up – the government has likely been investigating the matter for some time, perhaps even years, before you find out about it. You will have to quickly get up to speed on the facts and issues, as well as find out who the most knowledgeable employees are, where the information is kept, and the costs to the company of obtaining that information (including obtaining backup tapes, etc.).

Subpoenas/CIDs for Materials (Documents and Data)

As soon as you have that information, you should contact the government to discuss the government’s request. This is the time to convey your commitment to
responding to the subpoena in general (while not necessarily agreeing to respond to every part of the subpoena) and your interest in resolving the underlying issues (of course, “resolving” doesn’t necessarily mean “settling,” but resolving the issues may include explaining to the government why it has either or both the facts and the law wrong).

Because the government often has scarce resources to actually review all the information requested in a subpoena, particularly one that follows the “kitchen-sink approach,” you can suggest an approach that makes sense both for you and the government, such as limiting the initial production to a certain time period, issue, or geographic region. If you present the request as part of the joint effort to get to the bottom of the issue as quickly and expediently as possible, you stand a better chance of getting the government to agree.

You may also consider doing a limited internal investigation and agreeing to turn over the results to the government. If so, you may consider fashioning the scope and method of the investigation jointly with the government. Since you will have to do at least some amount of investigation to determine the facts, you may not have to expand that effort too broadly beyond what you would be doing anyway. Of course, you will have to consider whether you are willing to waive privilege, but there are ways to get around that issue, such as providing the government with a factual oral overview and factual backup.

If the costs of production are substantial (either financially or in terms of the effort required to obtain the materials), bring that to the government’s attention. Although the government may not be sympathetic to your predicament, if you can
demonstrate that the effort will be unduly burdensome and you suggest a reasonable alternative, you may be able to convince the government to hold off on at least part of its request until after you produce a smaller universe of materials. Once the government has reviewed that smaller portion of the requested materials, you may be able to have a discussion about the merits (or lack thereof) of the underlying case. If you are responding to a CID, and in the absence of much law concerning CIDs, the government may be reluctant to create bad law by filing a Petition to Enforce the CID when you have provided responsive materials and a plan to reduce the burden of providing additional materials. In the alternative, if the request is overly broad, you may consider filing a Petition to Modify or Set Aside the Demand. Once again, there is not very much case law, so the parameters of CID requests have not been clearly established. Any such petition must be filed on the earlier of 20 days after service or before the response date.

If the request is made through a CID, you should also be aware that the government is authorized to share the information with relators and their counsel. Although the Department of Justice requires internal reporting on whether the information is going to be shared with relators, that information is not public. You should, therefore, assume that the information will be shared. If the information you are providing contains competitively sensitive, business proprietary information, you should advise the government of that fact.

Testimony – Interviews, Subpoenas, CIDs

After the government has had a chance to review your materials, or often concurrently as the government is reviewing them, you will likely receive a request from
the government to talk to your employees. If you haven’t done so already, you will have to determine whether it is necessary or advisable to have separate counsel retained for employees. Counsel for the company is typically company counsel only. If the company decides that it will retain counsel to represent its employees in the investigation (as it often does), the question becomes which witnesses may be represented by so-called pool counsel and which ones require their own individual counsel.

Certainly if the government has identified any employee as a target – and in some cases where the employee has been identified as a subject – that employee will need his or her own counsel. Employees who are identified as purely fact witnesses, on the other hand, may be represented by pool counsel, who is an attorney retained and available to represent a number of individual employees who desire legal representation at the company’s expense. Although the company reimburses pool counsel for fees and costs associated with this representation, it is critical to note that pool counsel’s loyalties and duties lie with the individuals represented and not with the company. Meanwhile,

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13 Because company counsel typically represents the company only, company counsel who conduct an internal investigation should provide all employees who are interviewed with adequate and clear warnings at the beginning of each and every interview to ensure that the employee understands that counsel represents the company, that the purpose of the interview is to enable counsel to provide legal advice to the company, and that while the information obtained through the interview is privileged, the company holds that privilege and may decide to waive it later and share the information with the government. These warnings are typically referred to as corporate Miranda warnings or Upjohn warnings, named after Upjohn v. United States, 449 U.S. 383 (1981). See also Model Rules of Professional Responsibility, Rule 1.13, Organization as Client (“(f) In dealing with an organization’s . . . employees . . . or other constituents, a lawyer shall explain the identity of the client when the lawyer knows or reasonably should know that the organization’s interests are adverse to those of the constituents with whom the lawyer is dealing.”).
individual employees are always free to, and sometimes (although rarely) do, retain their own counsel of their choice at their own expense.

Because there is still very little law about CID proceedings, it is unclear whether the Federal Rules of Civil Procedure apply, what role counsel plays, the rights of individuals, or the use of CID testimony if the matter proceeds, either with a Department of Justice intervention or if the relator goes forward on his or her own.

**Interrogatories – CIDs**

Although it may be hard to imagine having to respond to interrogatories before you have even been served with a complaint, the CID section of the False Claims Act allows the government to issue interrogatories, even before the government files a complaint or intervenes in an already filed *qui tam*, to anyone with information relevant to a False Claims Act investigation. Unlike the discovery requirements in the Federal Rules of Civil Procedure, there is no express limit on the number of interrogatories allowed. Again, like documents or CID transcripts, responses to interrogatories can be shared with relators.

**Cooperation**

The government does not consider simply providing information requested through a subpoena, CID, or other process as cooperation; rather, it is what the government expects and requires. The question of whether to go beyond that and provide information, for example, about the actions of a company employee (or group of employees) or to provide the results of an internal investigation will vary by the facts presented in each individual matter. Will it be helpful to the company in the long run? Is
there likely to be some corporate resolution for which the company will want credit for cooperation?

Here’s the Department of Justice’s official view on the role of cooperation in making criminal charging decisions:\(^\text{14}\):

**The Value of Cooperation**

General Principle: In determining whether to charge a corporation and how to resolve corporate criminal cases, the corporation’s timely and voluntary disclosure of wrongdoing and its cooperation with the government’s investigation may be relevant factors. In gauging the extent of the corporation’s cooperation, the prosecutor may consider, among other things, whether the corporation made a voluntary and timely disclosure, and the corporation’s willingness to provide relevant information and evidence and identify relevant actors within and outside the corporation, including senior executives.

Cooperation is a potential mitigating factor, by which a corporation – just like any other subject of a criminal investigation – can gain credit in a case that otherwise is appropriate for indictment and prosecution. Of course, the decision not to cooperate by a corporation (or individual) is not itself evidence of misconduct, at least where the lack of cooperation does not involve criminal misconduct or demonstrate consciousness of guilt (e.g., suborning perjury or false statements, or refusing to comply with lawful discovery requests). Thus, failure to cooperate, in and of itself, does not support or require the filing of charges with respect to a corporation any more than with respect to an individual.

On the civil side, the value of cooperation is not officially delineated, but one must glean that there is potential value in cooperating by perusing press releases referencing the defendants’ cooperation\(^\text{15}\) or speeches made by Department of Justice

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\(^{15}\) For example, see the press release describing a settlement between the Department of Justice and Office Max, [http://www.justice.gov/opa/pr/2005/May/05_civ_278.htm](http://www.justice.gov/opa/pr/2005/May/05_civ_278.htm).
officials about the benefits of cooperation. For example, in 2012, Associate Attorney General Stuart Delery made this remark about cooperation:\(^{16}\):

> [T]his approach to potential *qui tam* litigation ignores the benefits of working collaboratively with the government in its fraud investigations. Most defendants in FCA matters have come to recognize that there is an enormous benefit to be gained by avoiding what will likely be costly and protracted discovery, trial, and the mandatory treble damages and penalties that will be assessed if the government prevails.

The more thorough and effective the job defense counsel do investigating the case and presenting their clients’ views of the applicable facts and law, the more likely it is that we will find these defenses persuasive, and the more credit your clients will get from the federal government in negotiated resolutions. And, I might add, because disclosure and cooperation show a sincere interest in cleaning house – and ensuring a culture of doing the right thing – they can help companies demonstrate the necessary responsibility to continue participating in government programs and contracts.

In reality, cooperation may get you a lower multiplier or a smaller time period or universe of conduct (of course, you will then get a narrower release, which is a different issue), but it will depend on with whom you are negotiating, and you won’t know the result of your cooperation until after you have cooperated.

*Voluntary Disclosure*

A close cousin of cooperation, voluntary disclosure, may be an appropriate path to take in the right case. While a voluntary disclosure made before an investigation even begins is likely to get you the most credit for coming forward, it is not too late to make a voluntary disclosure after an investigation has begun. It may be that you are being investigated about one issue and, in the course of investigating that issue, you discover

another separate issue. If you think it is likely that you will be paying to resolve the original issue at some point and that the second issue is also a problem, you may want to come forward on the second issue.

There are numerous paths to follow in making a voluntary disclosure, including the more formal ones set forth by HHS-OIG\(^\text{17}\) and CMS\(^\text{18}\) (for Stark violations). Alternatively, as long as your company has some connection to the district, you can make a disclosure to the U.S. Attorney’s Office of your choice (either one already investigating, one in your district, one with whom you’ve enjoyed a good relationship, or one you have heard is sympathetic to voluntary disclosures and likely to be willing to negotiate a fair and good resolution).

**Making Your Case**

After you have had the opportunity to learn the facts and the applicable law, you may want to discuss your view of the matter with the prosecutors. If you have a great legal defense (perhaps there’s a valid advice-of-counsel defense, for example), don’t wait until later to bring it to the government’s attention. If you’re right, the case may be over and no one on either side will have to spend time unnecessarily. It is often helpful to set up a meeting to discuss your perspective on the case with the prosecutors. If there is an agent who has been especially gung ho, you may want to request that the agent attend, as

\(^{17}\) [http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf][17]

\(^{18}\) [https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/downloads/6409_srdp_protocol.pdf][18]
well. If the matter is civil and being handled by a local civil AUSA and a Civil Fraud attorney, you want both of them to attend. Similarly, if there is a criminal investigation and an attorney from Consumer Protection Branch is involved, that attorney should also participate. If the investigation includes a NAMFCU team, they should also attend.

From the company side, who attends may depend on the subject (for example, if you are talking about the company’s great compliance program, you may want to have the compliance attorney or officer present), and that decision may also depend on the personalities of in-house counsel and executives. If, for example, you are speaking about the new leadership at the company, focusing on the steps that they have taken to clean house and to strengthen compliance efforts going forward, and you have an executive with impressive credentials who is credible, you may want to bring him or her to show how seriously the company is taking the matter. On the other hand, if your executives do not convey that credibility and sincerity, then bringing them to the meeting would probably be a mistake.

**The Resolution Stage**

There may come a time when you decide that it makes sense to attempt to resolve the matter. If there is a criminal case, generally you will want to resolve that matter first. Of course you will try to get the prosecutor to decline to pursue the criminal case at all, but if you are unable to do so, you will face issues of negotiating which entity and/or individuals will plead guilty, to what charges, and covering what period of time. All of those decisions have potential collateral consequences, including exclusion issues and effects on any potential civil case and follow-on of third-party or state cases.
A resolution with the government resolving criminal and civil matters is often referred to as a global resolution. If you wish to obtain a global resolution, you will need to request one. The AUSAs are not permitted to initiate such a resolution. Rather, the defense must initiate by making the request, and the government will often respond by sending a letter confirming the request. Global resolutions typically include not only criminal and civil liability, but also resolution of exclusion matters and frequently involve separate Corporate Integrity Agreements negotiated with HHS-OIG.

In resolving criminal and civil matters, it is important to keep in mind that the criminal and civil AUSAs must meet different burdens of proof, can impose different sanctions, and are working toward different policy goals. While civil liability needs to be established by a preponderance of the evidence, the settlement negotiations and agreement typically focus most directly on the damages calculation, as discussed more fully below. On the criminal side, the government is required to establish liability beyond a reasonable doubt. As a condition of entry of the plea, a criminal defendant is typically required to admit the criminal conduct charged, and often the defendant is required to allocute to specific, detailed factual basis questions in open court that establish the defendant’s guilt for the crimes at issue. Written plea agreements also may include a statement of facts and/or admissions by a defendant that the facts establishing liability are all true and that the government could prove those facts through admissible evidence if the matter were to proceed to trial. While there is usually no room to negotiate the actual language in any criminal charging document, a defendant may be
able to negotiate some of the other terms of a plea agreement. The form and standard language of plea agreements will vary by district.

For both the criminal loss calculation and civil damages, there are frequently numerous ways to calculate the range of potential payment for restitution, fines, and damages. In addition to variations in methods, there is also a range within which to negotiate the multiplier under the sentencing guidelines and/or the damages multiplier under the False Claims Act. These amounts, while negotiable, often follow certain unwritten rules of thumb.

On the criminal side, Chapter 8 of the United States Sentencing Guidelines applies when the defendant is an organization or company. As set forth in the Guidelines, the first priority is making any victims whole and so, whenever practical, courts are required to order the defendant company to remedy any harm caused and make victims whole. The Guidelines also set forth itemized criteria that are used to calculate the fine range, which is based on theseriousness of the offense and the culpability of the company. The seriousness of the offense, in turn, is determined by the greatest of gain to the company, the loss to the victims, or the amount in the Guideline offense table.

While this all sounds very formulaic, the Guidelines are merely advisory, and there is often a fair amount of play in deciding how to apply the criteria, determine each factor, and ultimately calculate the scores or amounts. Moreover, the determinations on each of the individual factors, when combined, can lead to extraordinarily different outcomes in the calculated scores or amounts. As for calculating the fine alone, for example, there are various ways to calculate the “gain” to the defendant company or the
“loss” caused by the company’s conduct. Among other things, the number will change – and often the change is significant – based on the time period that is used, as well as whether any set-offs are applied.

Application of the multiplier often has a dramatic impact, and therefore the calculation of the multiplier is of critical importance. The multiplier, in turn, depends on the calculation of a company’s culpability score, which results from consideration of six factors, including four that increase a company’s ultimate punishment and two that mitigate a company’s punishment. The four factors that increase a company’s punishment are involvement in and tolerance of the criminal activity; any prior history of misconduct by the company; whether the conduct involved the violation of any order or condition of probation; and whether the company obstructed justice. The two factors that mitigate against the ultimate punishment are whether the company has an effective compliance and ethics program and whether the company self-reported, cooperated, or affirmatively accepted responsibility for its criminal conduct.

The culpability score will then be used to determine the applicable minimum and maximum multiplier, which will then be used to determine the minimum and maximum criminal fine range. Ultimately, the fine imposed typically falls somewhere in the criminal fine range, and where it falls in the range will be based on such factors as the company’s role in the offense, any collateral consequences of conviction, any non-pecuniary loss caused or threatened by the offense, and whether the offense involved a vulnerable victim, among various other factors. Again, while this all sounds very precise and mathematical, there is lots of room for negotiation in the various categories.
On the civil side, although the False Claims Act provides for treble damages and mandatory penalties of $5,500-$11,000 per claim, if you are negotiating resolution before the government has filed a complaint or intervened, the government will usually waive the penalties and agree to a damages multiplier between double and treble. If there is also a related criminal case, the government mantra will be that civil damages must be trebled. While you may not be able to negotiate a lower multiplier, you may be able to negotiate applying treble damages to the usually smaller universe of damages that overlaps with the criminal case (for example, the criminal case may involve a shorter period of time or different conduct) and double damages to the rest.

If your company has an inability to pay double damages or higher, you may be able to negotiate a smaller multiplier, depending on your financial situation. In order to do so, however, you will have to complete government financial forms, certify their accuracy, and provide tax returns.

For large civil settlements, another unwritten rule is the government’s addition of interest (usually at the current Medicare trust fund rate) from the “handshake date” until the agreement is signed and payment actually made. Since the time lag between agreement in principle and payment can be months, for a large settlement, the interest amount can be substantial.

You may want to make payment over time. If you would like to make payments in installments within a period of less than a year, you may be able to get the government to agree. If, however, you would like to make payment over a longer period of time, the
government will insist that you demonstrate your financial inability to make the payments by making you go through the process described above.

On the civil side, in addition to the issue of damages, the standard civil settlement agreement includes numerous boilerplate provisions that may not be applicable but that the Department of Justice will insist must be included anyway. For example, the Department of Justice requires an “unallowable costs” provision for exclusion of certain costs – such as the cost of the investigation, payment of the settlement, and costs of any audits and civil investigations of matters covered by the Corporate Integrity Agreement – from any government contract accounting, even if there is no applicable government contract.

The “covered conduct” section of the agreement is the major section open to negotiation. The broader the covered conduct, the broader the release will be, as the settlement agreements usually provide a release for the covered conduct. You may also be able to negotiate the scope of the entities and individuals included in the release; for example, settlement agreements can include current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations or divisions; current and former owners, officers, directors, employees, and affiliates; and predecessors, successors, transferees, and assigns of any of them. You can negotiate the release to include the False Claims Act; the Civil Monetary Penalties Law; the Program Fraud Civil Remedies Act; any statutory provision creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present
authority to assert and compromise; and common law theories of payment by mistake, unjust enrichment, disgorgement, and fraud.

If you have reached an agreement with HHS-OIG, the civil settlement can also contain a release of HHS-OIG’s administrative remedies including exclusion. Additionally, if the matter involves payment of damages to other federal agencies, Tricare and OPM can also agree to have releases of their exclusion or debarment authority for the covered conduct.

If you are also paying a portion of Medicaid\textsuperscript{19} damages to the states, the federal settlement agreement will usually reference the amount to be paid to the states and the separate Medicaid state agreements that will be executed by each state that agrees to participate in the resolution. The separate state agreements will usually cover Medicaid damages only and not any additional state-funded programs of consumer protection-type damages under state unfair trade practice or deceptive practice-type causes of action.

Once you have reached an agreement in principle on terms, the government team must still get approval from a number of agencies and people. On the criminal side, the resolution will have to be approved by the criminal supervisor in the U.S. Attorney’s Office and perhaps higher levels of supervision, up to and including the U.S. Attorney for

\textsuperscript{19} The Medicaid program is a joint federal-state program. The portion contributed by the federal government varies by state. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Financing-and-Reimbursement/Financing-and-Reimbursement.html

The federal portion of the Medicaid damages is included in the amount paid to the United States; the state portion of the Medicaid share of the settlement is paid to the states.
the relevant district, depending on the Office and the nature of the resolution. If a Food, Drug and Cosmetic Act violation is being resolved, approval is also obtained from the Consumer Protection Branch and the Assistant Attorney General for the Civil Division (although if it is a criminal resolution, the head of the Civil Division is also involved because the Consumer Protection Branch is in the Civil Division). The civil supervisor in the U.S. Attorney’s Office (and possibly higher-level supervisors) and the supervisor in Civil Fraud at the Department of Justice (and possibly higher-level supervisors) must approve the civil resolution over $1 million. In addition, all affected agencies, the NAMFCU and the states (if there are state Medicaid claims), and the relator(s) and their counsel (if there are relators) must also approve. As you can imagine, this process can take some time even after you have negotiated actual resolution language.

The relator’s share of the federal portion of the civil settlement is negotiated separately between the Department of Justice and relator’s counsel, and it will range from 15% to 25% in a case in which the government intervenes and between 15% and 30% if the government has not intervened. The Department of Justice still looks to guidelines it issued in 1996 to determine the relator’s share, which include factors to increase or decrease the share. Some of the factors are tied to the relator’s conduct, e.g., did the relator promptly report the fraud, provide substantial assistance, make a credible witness, and/or cooperate with the government (which are factors that increase the relator’s award), or, to the contrary, did the relator substantially delay reporting the fraud, have

little knowledge of the fraud, participate in the fraud, or hamper the government’s efforts (which are factors that decrease the relator’s reward). The guidelines also include consideration of factors such as the size of the recovery, the stage at which the case settled, the breadth of the underlying fraud, and whether there was a safety issue. As a practical matter, the Department of Justice will focus on the size of the recovery in determining the amount of the relator’s share; large recoveries will yield relators’ shares closer to the low end of the range, while smaller recoveries are more likely to yield higher percentage recoveries.

There are often multiple relators involved in a case, and sometimes those _qui tam_ cases are filed in multiple jurisdictions. Although the first-to-file requirements in the False Claims Act might cast doubt on the viability of subsequent complaints, the Department of Justice is often reluctant to take on that battle. There are often complicating factors, including that the complaints are usually not identical (some may involve different time periods, different geographic areas, and variations on alleged schemes); also, different complaints may each provide additional useful information. Rather than fighting battles with relators, when it comes time for resolution, the Department of Justice will often suggest that relators work out an agreement in which the Department of Justice will pay the relator who filed the first complaint, and then that relator will then share the recovery with the additional relators based upon an agreement among them. Each relator, however, will have to agree that the recovery is fair, adequate, and reasonable and that their complaint will be dismissed with prejudice.
In addition to the relator’s share, relator’s counsel will negotiate attorneys’ fees separately with you. Although relator’s counsel will have a large contingency fee agreement with the relator, they will also expect the statutory attorneys’ fees to be paid by the defendant.

When everything is signed, you may have some concerns about the potential Department of Justice press, including whether there will be a press conference and what the press release will say. Although the Department of Justice says it will not negotiate press, you can ask whether there will be a press conference and, if so, when it will be held, and you can also request review of the press release in advance. While the practice varies from Office to Office and, indeed, even among prosecutors, you may be able to go to the U.S. Attorney’s Office to review the press release for the purpose of correcting any factual errors in advance of the release of the document to the public.