

## A Civil Investigative Demand Issued to You or Your Medical Practice is Serious Business. Understand Your Level of Risk Before Responding to the Government's Investigation



**(September 17, 2019):** The False Claims Act (31 U.S.C. §§ 3729-3733) is the primary civil enforcement tool relied on by the Federal government. It has a long and storied history, going back all the way to the Civil War.<sup>[1]</sup> Prior to 1986, the statute was only infrequently utilized by law enforcement. That changed with the enactment of the **“False Claims Amendments Act of 1986.”**<sup>[2]</sup> Among its many changes, the 1986 Amendments Act authorized the Attorney General to issue *Civil Investigative Demands* in connection with the investigation of False Claims Act cases. Over the years, Civil Investigative Demands have greatly bolstered the effectiveness of the government's ability to examine alleged violations of the False Claims Act.<sup>[3]</sup>

In 2009, Congress further expanded the use of Civil Investigative Demands when it passed the **“Fraud Enforcement and Recovery Act of 2009”**<sup>[4]</sup> (FERA). Among its various provisions, FERA authorized the Attorney General to delegate his authority to issue Civil Investigative Demands to other Department of Justice (DOJ) officials. The Attorney General subsequently issued a directive in 2010 which delegated his authority to issue Civil Investigative Demands to the Assistant Attorney General for the Civil Division. This directive also permitted the Assistant Attorney General for the Civil Division to redelegate the authority to issue Civil Investigative Demands to other DOJ Officials, including United States Attorneys.<sup>[5]</sup>

From a practical standpoint, the re delegation of authority to issue Civil Investigative Demands from the Office of the Attorney General to the 94 United States Attorneys Offices has greatly expanded the issuance of Civil Investigative Demands around the country. This article examines the government's use of Civil Investigative Demands as an investigative tool and discusses the steps you should take if the government issues one to you or your health care organization.

**[For additional guidance on the risks presented when dealing with parallel civil and criminal investigations, you may wish to review our [article](#) titled **“Have You Received a Civil Investigative Demand (CID)? How Should a Health Care Provider or Supplier Respond When Receiving a Civil Investigative Demand?”**]**

### I. What is a Civil Investigative Demand?

A Civil Investigative Demand is essentially a judicially enforceable administrative subpoena<sup>[6]</sup> that can be issued by a Federal prosecutor to obtain documentary materials and other information that may be in your possession, custody or control that the government believes may be relevant to an investigation of possible violations of the False Claims Act. A Civil Investigative Demand is only issued in connection with an ongoing False Claims Act investigation.

When issued to you or your medical practice, this investigative tool can be used to require that the subject (recipient individual or entity) of a Civil Investigative Demand:

- ***Produce such documentary material for inspection and copying,***
- ***Answer in writing written interrogatories with respect to such documentary material or information,***
- ***Give oral testimony concerning such documentary material or information,***<sup>[7]</sup>  
***or***
- ***Furnish any combination of such material, answers, or testimony.***

## **II. Are You or Your Medical Practice the Target of False Claims Act Investigation?**

If you are sent a Civil Investigative Demand, it doesn't necessarily mean that you are believed to have violated the False Claims Act. It's possible that a Federal prosecutor believes that you are a mere witness or a custodian of the records or other information that is relevant to the government's False Claims Act investigation. If you are the subject or target of a False Claims Act investigation, it is quite common for the Assistant U.S. Attorney handling the matter to clearly identify you or your medical practice as such when issuing a Civil Investigative Demand. While the language utilized by the government may vary from case to case, letters sent to physicians and other health care providers / suppliers will typically state something along the lines of:

***“This False Claims Act investigation concerns allegations that you, your medical practice, your employees, contractors, and agents, as well as other individuals or entities violated or conspired to violate the False Claims Act by submitting claims to Federal health benefit program for which you were not entitled to receive payment.”***

After investigating suspected violations of the False Claims Act, the Attorney General (through his

or her designee) may either bring a civil suit for violations of the False Claims Act **OR** elect to intervene in a *qui tam* case that has been brought by a private party. Importantly, once the government either files a False Claims Act complaint or intervenes in a *qui tam* that has been filed, it loses its authority to issue a Civil Investigative Demand.<sup>[8]</sup>

### **III. Do I have to Comply with the Requirements Set Out in a Civil Investigative Demand?**

The evidence sought by a Civil Investigative Demand may be quite extensive and will likely include demands for documentary materials, electronic records and written responses to interrogatories. Unfortunately, it may be quite costly and time-consuming for you to assemble the information requested and fully comply with the specifications set out in a Civil Investigative Demand. Should you fail to comply with a Civil Investigative Demand, the government will likely file a petition in Federal District Court seeking judicial enforcement of the request.<sup>[9]</sup> As the government's utilization of Civil Investigative Demands has increased, we have seen a number of challenges raised by recipients.

In one recent case, Federal prosecutors issued a Civil Investigative Demand in connection with their investigation of whether a physician had violated the Anti-Kickback Statute and Stark (which, depending on the facts, may also constitute a violation of the civil False Claims Act).<sup>[10]</sup> The respondent recipient of the Civil Investigative Demand, a California-based orthopaedic surgeon, refused to comply with the government's request, arguing that the DOJ lacked the authority to enforce the Civil Investigative Demand due to the fact that the government's had allegedly entered into settlement communications with a related party. Essentially, the respondent argued that the government's settlement discussions with a related party constituted a determination that a basis for the physician respondent's liability was present. Therefore, the respondent physician took the position that the government had an obligation to move forward with litigation rather than continue to investigate. In this case, since the government had not yet initiated a civil action and had not made an election related to actual *qui tam* litigation, the District Court that the Civil Investigative Demand should be enforced.

### **IV. Risks Presented in Parallel Civil and Criminal Investigations of Your Conduct:**

Although the issuance of a Civil Investigative Demand is reflective of the fact that a civil False Claims Act investigation is underway, it is important to keep in mind that the government may also have an open, ongoing criminal investigation related to the conduct that is under review. In recent years, this has become quite common, due in large part to more effective coordination efforts between civil litigators and criminal prosecutors in U.S. Attorneys Offices around the country.

It is the policy of the DOJ that its components (including U.S. Attorney's Offices) employ a coordinated approach to litigating affirmative matters from the initial intake, throughout the

investigation and to resolution.<sup>[11]</sup> DOJ requires “**early, effective and regular communication**” between all of its litigating components in order that it considers all potential remedies. Consultation between the Department’s civil and criminal attorneys, together with agency attorneys, are promoted to permit consideration of the fullest range of the government’s potential remedies and promotes the most thorough and appropriate resolution in each case. (criminal, civil, regulatory or administrative).

In some instances, concurrent criminal and civil investigations of individual misconduct are pursued. When this occurs, it is DOJ policy for the litigating components to coordinate the investigation and potential resolutions among themselves and with other stakeholders to the extent that the law permits. For example, criminal Assistant U.S. Attorneys are encouraged to use Administrative Investigative Demand (AID) subpoenas instead of Grand Jury subpoenas so that information obtained can be freely shared with their civil counterparts. Similarly, civil Assistant U.S. Attorneys are required to share the information they obtain in response to Civil Investigative Demands and / or *qui tam* investigation with their criminal colleagues. Coordination is extended to all aspects of the investigation including consideration as to the apportionment of fines, penalties and/or forfeitures and the avoidance of the duplicative fines, penalties and/or forfeiture in its resolution. Parallel actions are also intended to facilitate the Department’s efforts to hold individuals as well as corporations accountable for malfeasance.

As earlier discussed, the fact that you are the recipient of a Civil Investigative Demand does not necessarily mean that you are the target of a government False Claims Act investigation. Instead, you may be considered a subject of the government’s False Claims Act investigation. Finally, you may be a mere witness. Ultimately, a Federal prosecutor may choose to issue a Civil Investigative Demand if he or she believes that you have documentation or other materials that are relevant to the government’s investigation of possible violations of the False Claims Act.

A Civil Investigative Demand cannot be issued to investigation allegations that are solely criminal in nature (for example, the fraudulent billing of health care services to a private payor). However, if a bona fide investigation of possible civil false claims is present, this tool can be used to investigate potential False Claims Act violations and other conduct that may constitute a violation of criminal law. In light of the nature of parallel proceedings, there are a number of risks that you should take into account when responding to a Civil Investigative Demand. Several of these risks include:

- **Federal Anti-Kickback Statute (42 U.S.C. 1320a-7b(b)).** The Federal Anti-Kickback Statute<sup>[12]</sup> makes it a crime to *knowingly* and *willfully* offer, pay, solicit, or receive remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to purposefully induce or reward referrals of items or services payable by a federal health care program. Simply put, it is against the law to pay or provide anything of value in an effort to induce referrals or business related to a federal health care program. While for many years the Federal Anti-Kickback Statute and the civil False Claims Act were long viewed as separate and distinct enforcement tools, over the past 20 years, the enforcement landscape has

slowly changed. Starting in the early 1990's, whistleblowers began asserting violations of the False Claims Act in cases that would typically be pursued as a criminal anti-kickback violation. These cases often involved fact patterns where a party was alleged to have violated the Anti-Kickback Statute *and*, in the process, billed for services that were allegedly medically unnecessary (or, in some instances, worthless) and made a false express and / or implied certification to the Medicare or Medicaid program. The 2010 passage of the Affordable Care Act (ACA) obviated the need to bootstrap a violation of the Anti-Kickback Statute into a violation of the civil False Claims Act. Under the ACA, a claim submitted in violation of the Federal Anti-Kickback Statute now automatically constitutes a false claim for purposes of the civil False Claims Act. Providers need to keep in mind that even though a kickback violation may also be pursued under the False Claims Act, that does not preclude the government from prosecuting individuals and entities for violations of the Anti-Kickback Statute.

- **False Statements Involving Health Care Programs (18 U.S.C. § 1035)**. Several examples we have seen have involved the (a) the misrepresentation of the provider of a medical service, (b) the misrepresentation of a non-covered service, and / or (c) the billing of services performed by unlicensed staff. Each of these examples may give rise to criminal and / or may also be pursued under the civil False Claims Act:
- ***Misrepresentation of the Provider of a Service***. This improper billing practice is still commonly found in both medical and dental practices around the country. ***In the cases we have seen, "fraud" wasn't the reason for the underlying misrepresentation on the CMS 1500 Claims form. In most instances, it was merely a matter of a credentialing delay.*** Although we have not seen a misrepresentation case of this type referred for criminal prosecution, it is important to remember that both CMS 1500s and ADA Dental Claim Forms Claims forms are typically electronically submitted to the health plan for payment. Depending on the facts, an aggressive prosecutor could argue that such conduct constitutes a criminal false statement under 18 U.S.C. § 1035 or even wire fraud under [18 U.S.C. §1343](#).
- ***Misrepresentation of a Non-Coverage Service***. This type of improper billing practices occurs when a medical or dental practice has mischaracterizes a non-covered service as a covered service. Keep in mind, the definition of a non-covered service varies from payor to payor. Additionally, the list of non-covered services under a specific payor's policy may change from year-to-year. In any event, it is important that health care providers regularly check to ensure that the services being provided qualify for coverage and payment.
- ***Billing for Medical or Dental Services Performed by Unlicensed Staff***. Perhaps the quickest way to get into trouble with both law enforcement and your State Medical Board or State Dental Board is to allow non-licensed individuals to provide care that may only be administered by qualified, licensed personnel. Earlier this year, the New York Attorney



General's Office announced the indictment, arrest and arraignment of a health care provider and four unlicensed individuals that the provider was permitting to perform medical related procedures on more than 100 Medicaid patients. From a false claims perspective, the billing of Medicare and / or Medicaid services by unlicensed staff would constitute the misrepresentation of the credentials of the staff member at issue and would not qualify for reimbursement.

These are only a few of the risks that you face when a government investigation of your business arrangements, and billing / coding practices is initiated. When responding to a Civil Investigative Demand, it isn't merely sufficient to produce the information requested. A careful analysis of your practices needs to be conducted ***on the front end*** so that any problematic conduct can be identified and assessed. Experienced health care legal counsel can then more effectively represent you and your practice.

## **V. How Should You Respond to a Civil Investigative Demand?**

For the reasons set out above, we strongly recommend that you engage counsel as soon as you receive a Civil Investigative Demand. Your attorney can then take the lead and contact the Assistant U.S. Attorney<sup>[13]</sup> handling the False Claims Act investigation. Additional steps you should take include, but are not limited to:

- ***Determine the nature of your involvement in the government's investigation.*** Does the government consider you or your practice to be a target, a subject or a witness? Are both civil and criminal allegations present? If the possibility of criminal culpability has been identified, it is essential that your legal counsel advise you on any steps needed to properly safeguard your interests.
- ***Don't turn what may be a civil problem into a criminal case.*** Steps should immediately be taken to ensure that no documentation (either paper or electronic) is destroyed, deleted or over-written. Your attorney can guide you in this document preservation process. The last thing you want to do is take an action in a civil False Claims Act investigation that might constitute a separate criminal violation (such as obstruction of justice). Once the proverbial fog lifts, your attorney will likely be able advise you whether it is permissible to resume getting rid of documents that have no bearing on the government's case.
- ***Have experienced health law counsel handle scope and timing negotiations with the government.*** Civil Investigative Demands are often excessively broad in scope and typically request large numbers of medical or dental records and claims information. Moreover, under the statute you have very little time to produce the materials being sought by a Civil Investigative Demand. Your attorney will likely try and work with the government attorney handling the investigation to obtain an extension of time in which to submit the requested documents.<sup>[14]</sup> Your attorney will also try and work with the government attorney to see if the scope can be narrowed (at least at first). Finally, your attorney will

want to try negotiate for the documents and information to be produced to be submitted on a “rolling” basis.

- ***Diligently work to identify and address the government’s concerns.*** It has been our experience that most Assistant U.S. Attorneys are willing to engage (at least in a limited fashion) in a discussion regarding the nature of the government’s concerns. This information can be crucial in assessing the conduct, responding to the government’s concerns, and, if necessary, preparing your defense(s) in the case. Keep in mind, at this point, the government hasn’t filed a False Claims Act complaint and hasn’t intervened in the whistleblower’s case (to the extent that one exists). Now is the time to do your very best to analyze the facts and respond to the allegations presented.
- ***Take care before “Certifying” your responses under the Civil Investigative Demand.*** As required under 31 U.S.C. § 3733(f)(1), when you produce documentary materials in response to a Civil Investigative Demand, it must be made under a “Sworn Certificate.” 31 U.S.C. § 3733(f)(1), The Sworn Certificate is required to state that:

*“. . . all of the documentary material required by the demand and in the possession, custody, or control of the person to whom the demand is directed has been produced and made available to the false claims law investigator identified in the demand.”* [\[15\]](#)

As with any certification made to the government, you must exercise caution when making the representations required under 31 U.S.C. § 3733(f)(1). Should your responses to the Civil Investigative Demand be false or misleading, the government may assert that you have made a false statement (assuming that the requisite level of intent can be shown).

As reflected by the risks discussed above, if you or your practice are the recipient of a Civil Investigative Demand, you should immediately contact a qualified health lawyer. The issuance of a Civil Investigative Demand raises a number of complex regulatory questions that must be fully vetted. Have you received a Civil Investigative Demand? **Give us a call for a free consultation. 1 (800) 475-1906.**

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**Robert W. Liles** serves as Managing Partner at the health law firm, Liles Parker, Attorneys and Counselors at Law. Liles Parker attorneys represent health care providers and suppliers in connection with False Claims Act issues and investigations. Have you received a Civil Investigative Demand? If so, we can help. [For a free initial consultation regarding your situation, call Robert at: 1 \(800\) 475-1906.](#)

[1] For additional background information on the False Claims Act, see [“False Claims Act Matters and Cases — An Overview.”](#)

[2] [Public Law 99-562](#). October 27, 1986. Senator Charles Grassley (R-Iowa) and Representative Howard Berman (C-California) led the drive to have these amendments passed. Several of the significant changes to the statute included, but were not limited to the following:

- Permitted the government to seek treble damages.
- Revised the statute’s qui tam provisions by increasing the incentives to whistleblowers disclosing allegations of fraud under the False Claims Act.
- Conferred authority upon the Attorney General to issue Civil Investigative Demands (CIDs) in connection with the investigation of False Claims Act investigations.

[3] Last Fiscal Year (FY 2018), the Federal government won or negotiated more than \$2.8 billion in judgments and settlements under the False Claims Act. Of the \$2.8 billion in settlements and judgments recovered by the Department of Justice this past fiscal year, \$2.5 billion involved the health care industry. Although the gross recoveries were almost \$600 less than what was collected in FY 2017, it is worth noting that an additional \$329 million was collected in health care related cases than last year. During FY 2018, 645 qui tam (whistleblower) cases were filed. About 87% of all new FCA matters pursued against entities involved in the healthcare industry were brought by relators.

[4] P.L.111-21 (FERA). FERA also permitted Federal prosecutors to share information obtained under a Civil Investigative Demand with **“any person”** (most typically a *qui tam* relator)(See 31 U.S.C. § 3733(a)(1) and with Federal prosecutors conducting criminal investigations if the Attorney General or designee has reason to believe that such person may be in possession, custody, or control of any documentary material or information relevant to a False Claims law investigation.

[5] In 2010, the Attorney General signed Order No. 3134-2010 (January 15, 2010).



[6] See *United States v. Markwood*, 48 F.3d 969, 975-76 (6th Cir. 1995) (finding FCA CIDs are administrative subpoenas); *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1087 (D.C. Cir. 1992) (treating FTC CID as administrative subpoena), cert. denied, 507 U.S. 910 (1993); *United States v. ASG Solutions Corp.*, No. 17-cv-1224, 2018 WL 1418023, 2018 U.S. District LEXIS 47716 (S.D. Cal., March 22, 2018) (Report and Recommendation of Magistrate Judge) (enforcement of FCA CID governed by standards for administrative subpoenas), adopted in full, 2018 WL 3471405, 2018 U.S. Dist. LEXIS 121013 (S.D. Cal., July 18, 2018).

[7] Under a Civil Investigative Demand, the government may seek oral testimony concerning the documents and / or information that you are producing. The oral testimony is handled like a deposition, the deponent is placed under oath and a stenographic record of the proceeding is kept.

[8] For example, in the case *United States v. Kernan Hospital*, No. RDB-11-2961, 2012 WL 5879133, 2012 U.S. Dist. LEXIS 165688 (D. Md., Nov. 20, 2012), the district court denied the government's Petition for Summary Enforcement based on the fact that the United States ***had already filed an FCA complaint in the case***. The District Court took this position even though the case had been dismissed (for failure to plead the alleged fraud with particularity) at the time the Civil Investigative Demand was issued.

[9] The scope of judicial review that is conducted by a District Court Judge when the government seeks to enforce a Civil Investigative Demand is very narrow. As the Ninth Circuit has stated:

*"[t]he scope of the judicial inquiry in . . . any . . . agency subpoena enforcement proceeding is quite narrow. The critical questions are: (1) whether Congress has granted the authority to investigate; (2) whether procedural requirements have been followed; and (3) whether the evidence is relevant and material to the investigation."* *EEOC v. Fed. Express Corp.*, 558 F.3d 842, 848 (9th Cir. 2009) (quoting *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076 (9th Cir. 2001)).

[10] *United States v. Picetti*, No. 2:19-cv-00049 KJM AC (E.D. California)(April 29, 2019).

[11] Justice Manual Chapter 1-12.000; updated in November 2018, See also, Memorandum entitled ***"Coordination of Parallel Criminal, Civil, Regulatory and Administrative Proceedings,"*** from the Attorney General to all Litigating Divisions and All Trial Attorneys, dated January 30, 2012, found as Civil Resource Manual 228 and Criminal Resource Manual 2464.

[12] Under the Bipartisan Budget Act of 2018 (effective February 9, 2018), Criminal penalties for acts involving Federal health care programs under 42 U.S.C. § 1320a–7b, including but not limited to the Anti-Kickback Statute, were increased from \$25,000 to \$100,000. Additionally, the maximum sentences for felonies involving Federal health care program fraud and abuse under 42 U.S.C. § 1320a–7b, including but not limited to the Anti-Kickback Statute, were increased from five to ten years.

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[13] Infrequently, we have seen prosecutors from the State Attorney General's Office issue a CID.

[14] Pursuant to 31 U.S.C. §3733, you will only have twenty days in which to respond to a Civil Instigative Demand, unless an extension is granted by the government. Additionally, if a request for oral testimony is being sought, you may have as little as seven days within which to respond.

[15] 31 U.S.C. § 3733(f)(1)(B).