Sixth Annual National Congress on Health Care Compliance

Concurrent Sessions IV

Internal Investigations and Self-Disclosure: Interactions Between Compliance Professionals, Outside Counsel and Government Representatives

"Compliance Officers and Outside Counsel"

Gabriel L. Imperato, Esq.
Broad and Cassel
Fort Lauderdale, Florida
Phone: (954) 764-7060
Fax: (954) 713-0965
Email: gimperat@broadandcassel.com

"COMPLIANCE PROGRAM OFFICERS AND OUTSIDE COUNSEL"

I. CONSIDERATIONS FOR COMPLIANCE OFFICERS AND OUTSIDE COUNSEL IN CONDUCTING INTERNAL INVESTIGATIONS OF COMPLIANCE MATTERS

A. What is the role of the compliance program officer and/or outside counsel in resolving a compliance matter for a health care organization?

B. When should outside counsel be retained to address an organization's compliance matter?

1. Is there a role for outside counsel in routine organizational compliance matters?

2. When should compliance officers seek the "advice of counsel" for an organization?

(a) Unclear or unreconciled legal application

(b) Resolution of conflict and outside counsel as organization messenger

C. Should all compliance matters be reviewed within the scope of the attorney-client privilege?

1. Internal investigations without an external parallel government investigation;
2. Internal investigations with an external parallel government investigation:

(a) Compliance matter involving issues which are the subject of the external parallel government investigation;

(b) Compliance matters involving issues which may be the subject of the external government investigation; and

(c) Compliance matter involving issues which are not the subject of the external parallel government investigation.

D. Should there be consultants retained to assist in the internal investigation and who should retain them?

1. Investigative Consultants

2. Expert Consultants

E. What is the role of a compliance officer during an internal investigation conducted by outside counsel?

1. Who should conduct the investigation?

(a) Compliance officer?

(b) Inside counsel?

(c) Outside counsel?

(d) Inside counsel and outside counsel?

(e) Compliance officer and outside counsel

2. Organization Representative and Liaison with outside counsel

3. Interviews and Document Production

F. What should be the scope of an internal investigation of a compliance matter?

1. Is the scope any different if there is or is not an ongoing parallel government investigation taking place?

G. What is the appropriate response when there is a "whistle-blower" in the midst of the matter being investigated by the organization?

H. What are the strategy options for dealing with a whistle-blower?

1. Review and respond to whistle-blower complaint

2. Voluntary (public) disclosure

I. What are the considerations which should be taken into account when contemplating a voluntary disclosure?

J. When is a voluntary disclosure appropriate?

1. Known overpayment?

2. Other misconduct?

K. When an organization contemplates a voluntary disclosure, to whom should such disclosure be made?

1. Department of Justice?

2. Office of Inspector General of Health and Human Services?

3. State Attorney General?

4. Fiscal intermediary or carrier?

L. What is the role of the organization's compliance officer and/or in-house counsel in a voluntary disclosure situation?

1. Participant/observer?

2. Affirmative representative of the organization?

3. Liaison to the government for corrective action and assurance of compliance?

M. What should be the role of the compliance officer and/or in-house counsel when an organization is under active external investigation by a Federal or state government agency?

N. Should the compliance officer be the representative of the organization with the government agencies?

II. CONDUCTING AN INTERNAL INVESTIGATION OF THE ORGANIZATION

A. Introduction

1. Federal government initiated investigations have led organizations to consider a response and strategy for managing an investigation.

2. Key components for response strategy to government scrutiny and liability for violations of Federal statutes include:

   (a) Conducting a self-evaluative internal investigation of those matters under scrutiny by the government, but also those matters which could cause exposure to the organization;[1]

   (b) The initiation of an internal investigation as part of such a strategy requires:

      (i) careful consideration;

      (ii) equally well thought-out methods and procedures; and

      (iii) an appreciation of the issues and pitfalls involved in this type of matter.

3. Information obtained through such an investigation may be transformed into documents suitable for criminal and civil pre-trial discovery and trial.

4. This discussion seeks to enumerate factors which should be taken into consideration when conducting an internal investigation of an organization related to potential violations of Federal statutes.

B. Scope and Accountability of Internal Investigation

1. The most important initial consideration to be taken into account when directing and conducting an internal investigation of an organization involves a clear understanding regarding the scope, method, accountability and reporting between:

   (a) the law firm directing the investigation;

   (b) the consultants conducting the investigation; and

   (c) the client organization which is authorizing the internal investigation

[1] "Investigations: Health Attorneys Outline How, Why Providers Should Conduct Investigations" Vol. 3 BNA Health Care Fraud Report No. 7, pgs. 320-21 (April 7, 1999) (citing comments made by Jan E. Murray, Vice President and General Counsel of Southwest Community Health Systems, Middleburg Heights, Ohio).

2. This is important considering:

   (a) those conducting an internal investigation will not be the most popular visitors with members of the organization;

   (b) the investigation may not necessarily result in positive findings and recommendations for the organization and/or key individuals in the organization; and

   (c) the investigation may identify new issues and liabilities for the organization.

3. The issues which should be raised in discussing the scope of the internal investigation with your client should include:

   (a) the subject matter to be addressed;

   (b) who the law firm will be accountable to within the client organization; and

   (c) who the investigative team will be accountable to within the client organization.

4. The reporting responsibility for the investigative team could be to:

   (a) a special committee of the Board of Directors, such as an audit committee;[2]

   (b) a committee of independent directors;

   (c) the in-house counsel for the organization; and/or

   (d) selective members of the management team, such as an organization's compliance official which is an implicit requirement of many corporate integrity agreements ("CIAs") with the government.

[2] An effective corporate compliance plan can also help shield a health care corporation's directors from civil liability stemming from a shareholders' derivative lawsuit. *See, e.g., In re Caremark International, Inc.,* 1996 Del. CH. LEXIS 25 (September 25, 1996).

5. This assessment will necessarily require a determination of the degree of independence/control which will be exerted by management over the internal investigation:

   (a) This obviously has implications for the credibility and effectiveness of the internal investigation.

   (b) The degree of credibility of the internal investigation also could have an extremely important impact on the level of cooperation and credibility which the organization may have with the government entities investigating the potential violations of Federal statutes.

6. An investigation, at a minimum, must collect the relevant facts associated with the issues within the scope of the investigation.

7. Additional issues which should be discussed at the outset with the organization:

   (a) the extent to which the internal investigative team will develop the facts and proffer conclusions based on those facts; and

   (b) whether conclusions of law should be drawn from those facts or whether they should be left to other parties and, perhaps, even other outside or inside counsel and/or management of the organization:

      (i) Any determination is not without risks, especially as it relates to strategy with the Federal or state government law enforcement authorities.

      (ii) This requires careful consideration at the outset and continued reassessment during the course of the internal investigation.

      (iii) Whether an official written report should be submitted to management outlining the factual and legal conclusions derived from the internal investigation should be considered and discussed with the client.

C. Matters of Privilege

1. Any internal investigation should preferably be conducted through outside counsel in order to maximize the privileged nature of the investigation and protect confidentiality and the integrity of the internal investigation:

(a) Information that counsel obtains may be protected by the attorney-client privilege, which protects communications of information between a client and the client's attorney. Upjohn v. United States, 449 U.S. 383, 389-90 (1991).

(b) Information that counsel obtains may also be protected under the attorney work-product doctrine, which protects from discovery documents or tangible things prepared in anticipation of litigation or for trial. Hickman v. Taylor, 329 U.S. 495 (1947).

(c) Information obtained by counsel also may be protected under the critical self-evaluative privilege. See Bredice v. Doctor's Hosp., Inc., 50 F.R.D. 249 (D.D.C. 1970), aff'd, 479 F.2d 920, (D.C. Cir. 1973). But the scope of this privilege is extremely limited and many jurisdictions do not recognize the privilege. See e.g., Payton v. N.J. Turn Pike Authority, 148 N.J. 524, 691 A.2d 321 (1997).

(d) Counsel may also retain experts and/or investigators to assist in gathering information. The expert or investigator must truly function as counsel's agent, and disclosures to the agent will be protected only if they are necessary to obtain informed legal advice. See In re: Grand Jury Matter, 147 F.R.D. 82 (E.D. Pa. 1992) (where the client's ultimate goal is not the receipt of legal advice, but is rather accounting, medical or environmental advice, the privilege is inapplicable).

(e) This does not mean that the conduct of the internal investigation is utilized to otherwise attempt to cloak documents which were previously not privileged, but it does mean carefully tracking what new information is gathered by the investigative team and ensuring that it will be privileged and confidential.

2. Issues of future disclosure must be considered:

   (a) Findings and conclusions may be disclosed to the government at a later date in the context of resolution of issues concerning potential violations of Federal statutes.

   (b) The very fact that such a disclosure may be contemplated requires realization that information gathered during the internal investigation may, ultimately, be shared with a third-party which could result in waiver of the attorney-client and work product privilege in other parallel civil or criminal proceedings. This can be a particular problem when parallel civil litigation arises, which is often the case when publicly traded companies are involved.[3]

3. Joint defense as a possibility:

   (a) Issues of privilege are also implicated when other organizations or individuals related to the organization may also have individual exposure for culpability for their own actions involving allegations of violations of Federal statutes.

   (b) a decision may have to be made at an early stage of the investigation regarding whether or not to enter into joint defense arrangements between the organization and such other entities and/or individuals.

   (c) This decision should consider how a joint defense agreement may limit discretion on the part of the organization regarding potential disclosure of information gathered during the internal investigation to the government authorities.

   (d) This decision should also consider how a joint defense agreement may be viewed by those government authorities conducting the investigation.

[3] David W. O'Brien, *Managing A Government Investigation,* Insight (April 3, 1998) (citing *United States v. Lawless*, 709 F.2d 485 (7th Cir. 1983); *Admiral Insurance v. U.S. District Court,* 881 F.2d 1486 (9th Cir. 1989)).

D. Managing the Investigation

1. Another critical aspect of any internal investigation is defining the organization's expectations and managing those expectations as the investigation continues.

2. The investigative team and the organization should discuss and arrive at an understanding about:

   (a) the time frame for completion of the investigation;

   (b) the resources necessary to do so within that time frame;

   (c) what types of experts may be needed to be brought in during the course of the investigation both for gathering the facts and/or analysis of facts relevant to any potential violations of Federal statutes;

   (d) the potential scope of the problems to be addressed and whether it may include criminal, as well as civil and administrative liability under such laws as the health care fraud and abuse laws.

3. Continued updates on the progress of the investigation and some assurance that the client understands what will unfold as the investigation continues should be given.

4. If the internal investigation is being undertaken parallel to a government investigation consideration should be given to:

   (a) communicating with the government as to what the intentions of the organization are in this self-evaluative internal investigation; and

   (b) seeking cooperation from the government in either delaying or completing their own investigation in as orderly a manner as possible and with as little disruption to the day-to-day business affairs of the organization.

   (c) This is not only an important reason for conducting an internal investigation to begin with, but depending on the credibility and persuasiveness of your investigative team it is possible to obtain a level of cooperation from the government authorities who are presumably interested in

the same issues which the investigative team may be reviewing within the organization.

(d) The level of law enforcement interest in the issues which will be addressed during the internal investigation will play a large part in the strategy of the internal investigation and potentially the ultimate issue of self-reporting and voluntary disclosure of the information obtained by the organization in the context of achieving a resolution of the issues with law enforcement authorities.

E. Investigative Methodology

1. The investigative techniques and methodology should also be discussed thoroughly with the client organization so a clear understanding can be achieved concerning how the investigation will affect the organization and what level of cooperation can be expected from the organization.

2. The following issues should be addressed before the investigation begins:

(a) How many current or former employee interviews are likely?

(i) Who will contact former employees and what will they be told?

(ii) Who will be interviewed and where?

(iii) Who will conduct the interviews?

(iv) Do the employees to be interviewed have any legal exposure for their own actions and is the client willing to provide them with an attorney at a cost to the organization?

(v) What will happen if an employee refuses to cooperate?

(b) What documents have to be reviewed?

(i) Where are the documents and have they been secured?

(ii) How will they be categorized and organized?

(iii) Who will review these documents?

(c) Do any computers have to be downloaded and searched?

(i) Covertly or overtly?

(ii) Is there a local area network?

(iii) Laptops, portable PCs, palm pilots?

(iv) A wide area network?

(v) Electronic mail?

(vi) Where are the servers?

(vii) Can the hardware and software be secured?

(d) Will offices have to be secured and searched?

(i) How many and where and will the client be cooperative in such a search?

(e) Does your client's organization currently have a compliance program?

(i) A compliance officer?

(ii) Has any review or monitoring or auditing been conducted prior to the initiation of the internal investigation?

(a) If so, what were the findings and was corrective action taken?

3. This should not be the last time that you visit the question concerning your clients compliance program, because if there is an eventual settlement of issues with the government it will likely mandate the imposition of an "effective" compliance program.

   (a) The organization will be far better off in many respects by ensuring that its compliance program is "effective" before the government defines its effectiveness through the onerous requirements which have appeared in recent health care fraud and abuse settlement agreements.

   (b) Regardless of your client's line of business, an effective compliance program should mirror the recommended guidelines set forth by the United States Sentencing Commission in the Federal Sentencing Guidelines for Organizations, or the Model Compliance Guidances published by the OIG.

   (c) An effective compliance program can mitigate the fines, penalties and sanctions that your client organization may be subject to in any settlement negotiations with the government. [4]

[4] Those organizations which have in place a compliance plan may receive favorable treatment under the Federal Sentencing Guidelines ("Sentencing Guidelines"). Thomas F. O'Neil III & Adam H. Charnes, *The Embryonic Self-Evaluative Privilege: A Primer for Health Care Lawyers* 5 Ann. Health Law 33 (1996); David D. Queen & Elizabeth E. Frasher, *Designing a Health Care Corporate Compliance Program* 1-3 (David Miawsky & Phoebe Eliopoulos eds. 1995). The Sentencing Guidelines provide for reductions in the criminal sentence of an organization with a formalized program designed to detect and prevent violations of the law. *Id.*; *see also* U.S. Sentencing Guidelines Manual § 8C2.5 (f),(g) (1995). To receive the benefits of a compliance program, such program must be designed and implemented to be "effective" as that concept is used in the Sentencing Guidelines for organizations. These Sentencing Guidelines set forth seven standards for effective compliance programs. These standards include: 1) The organization must establish compliance standards and procedures reasonably capable of reducing improper conduct; 2) Specific high-level individuals within an organization should be assigned the overall responsibility to oversee compliance by the organization's employees with the standards and procedures; 3) The organization must use due care not to delegate substantial discretionary authority to individuals who have a propensity to engage in illegal activities; 4) The organization must take steps to communicate effectively its standards and procedures to all employees and other agents; 5) The organization must take reasonable steps to achieve compliance with the standards by utilizing monitoring and auditing systems and implementing a reporting system whereby employees can report suspect conduct within the organization without fear of retribution; 6) The standards must be consistently enforced with appropriate disciplinary mechanisms; and 7) After an offense has been detected, an organization must take reasonable steps to respond appropriately and to prevent further similar offenses. *Id.*

F. Directing, Conducting And Documenting The Results Of The Investigation

1. An important part of an internal investigation is providing the organization representatives with periodic (daily is recommended for large investigative matters) updates so that the client organization can be kept abreast of the status of the investigation:

(a) How should updates be made to the client? How often should they occur? Who should receive this information and otherwise be involved in this process?

(b) Formal presentation of facts to the client can be made while the investigation is in progress or an informal approach can be utilized depending on the preference of the parties.

(c) If updates on progress are to be in writing or whether they will merely be orally presented may depend on the extent to which such documents are potentially discoverable by third-party litigants.

2. The legal team must also make certain decisions for the investigative team such as:

(a) Whether to have one or two people present during interviews.

(b) Who should take notes and whether those notes should be memorialized in written interview memoranda.

(c) If the results of the interviews are to be put into written form, a decision must be made whether the investigative team should retain their original notes or dispose of them after the write-ups are finalized.

(d) A standard preamble should be used prior to interviews which states that the information gathered is to assist the law firm in providing legal advice to the client (the organization) and that the memoranda are not verbatim transcripts of the interview.

(e) The legal team should brief the investigators who will be conducting the interviews as to how the interviewees should be approached and what procedures should be

followed to ensure that the interviewee understands that the investigation is being conducted by the organization and use of information provided during the course of the interview will be determined solely by the company (i.e. waiver of privilege and disclosure to third party).

(f) Care should be taken when utilizing inside counsel because a party seeking disclosure may claim that inside counsel functioned as a non-lawyer when he or she obtained certain information or that inside counsel obtained the information in the ordinary course of business. See Teltron, Inc. v. Alexander, 132 F.R.D. 394 (E.D. Pa. 1990). This is one important reason why outside counsel is retained to conduct the internal investigation.

3. Generally, a corporation can use, as it deems appropriate, any information that it obtains through an internal investigation, including information obtained through employee interviews. Under ordinary circumstances, it is not necessary to provide explicit warnings to an employee as to the uses to which his or her statement may be put. Absence special circumstances, an employee does not have a reasonable expectation of confidentiality as to his or her communications with company counsel. See United States v. Furst, 886 F.2d 558 (3rd Cir. 1989). But where counsel has credible evidence indicating that the employee is engaged in wrongdoing, counsel should recommend that the employee be advised of:

(a) their right to consult with counsel prior to cooperating with the organization's internal investigation and

(b) of the consequences of failing to cooperate with the internal investigation

4. If the client has made a decision to cooperate with the government, or if the results of the investigation may be turned over to the government at some point in time, a decision must be made as to whether there will be a written or oral presentation of findings and what impact this may have upon waiver of the attorney/client and work product privileges

G. Conclusion

1. The completion of the internal investigation will then move the engagement into a phase of determining the extent of culpability for the organization and any current or former employees and what type of negotiations (if any) should be conducted with government representatives regarding resolution of culpability for the organization or these individuals

2. The organization, along with the attorneys directing the investigation and the investigative team, should consider whether to make a presentation of the facts to the government

   (a) It may be more useful in some cases for other outside counsel to negotiate any resolution of issues with the government based on the facts disclosed from the internal investigation which:

      (i) preserves the objectivity of the investigative findings and

      (ii) bolsters the credibility of those findings as a basis to negotiate a settlement with the government

3. There is nothing completely identical from one internal investigation to the other and the scope, methodology and strategy behind internal investigations will differ from client to client and case to case.

4. However, an internal investigation is an increasingly useful and necessary tool to deal with the onslaught of government scrutiny and investigations and potential liability associated with violations of the health care laws.

5. If used in an appropriate manner, an internal investigation can be successful in resolving issues that otherwise could cause considerable disruption and/or destruction to a health care organization.

6. The company must avoid any action that could be construed as obstruction of justice. See 18 U.S.C. §§ 1503, 1505, 1510, 1512, 1514, 1516, 1517 and 1518. Section 1512(c)(2) makes it a crime to "harass" another person, thereby dissuading such person from testifying or providing information to law enforcement officials.

Section 1512(b)(2) makes it a crime to corruptly persuade a person with intent to delay or prevent communication to law enforcement officials of information relating to a federal offense. Section 1518(a) makes it a crime to willfully prevent the communication of information relating to a federal health care offense to a criminal investigator. Thus, counsel or company officials generally should be wary of instructing corporate employees not to speak to government agents during an investigation. But see United States v. Farrell, 1997 U.S. App. Lexis 26281 (3rd Cir. Sept. 24, 1997) (Section 1512(b)(2) does not encompass a request from a co-conspirator not to cooperate and provide information to authorities absent evidence of corrupt intent).

III. VOLUNTARY DISCLOSURE

A. Introduction

1. Providers who have discovered that they have received overpayments from a Federal health care program have a variety of voluntary disclosure avenues available to them. Further, certain federal statutes and programs offer providers incentives to disclose voluntarily.

2. Depending on the totality of the facts and circumstances in each case, providers may choose to self-disclose to any of the following:

   (a) an intermediary or carrier;

   (b) CMS;

   (c) the OIG;

   (d) the appropriate state Medicaid Fraud Control Unit;

   (e) the state governing body that regulates the provider's practice; and/or

   (f) the Department of Justice (the "DOJ").

3. Providers should seek advice of counsel before voluntarily disclosing any matter to any of the entities listed above because the analysis of the Risks vs. Rewards of voluntary disclosure is unique to each case.

4. REWARD – In general the government encourages voluntary disclosure. The advantages of a voluntary disclosure are obvious:

   (a) It may engender sufficient goodwill with the government that the company may avoid criminal charges altogether; and

   (b) Even if criminal charges are brought against the company, it may be used as a potential mitigating factor under the sentencing guidelines to reduce the potential penalties.

5. RISK – There are significant risks in any disclosure:

   (a) Government does not guarantee that it will not prosecute voluntary disclosures. Thus, by making one, you put yourself completely at the mercy of the government's discretion; and

   (b) You are giving the government information which it is entirely free to use against your company in a criminal prosecution. In effect, you may be giving the government a smoking gun or otherwise disclosing problems of which the government may not be aware.

6. Once you make a disclosure, in order to get the full benefits of the disclosure, you are committed to "full and complete cooperation" with the government. This may well include providing information to be used against corporate employees, including high level executives, and the complete disclosure of privileged information, including any internal investigation.

   (a) The disclosure of the internal investigation or parts of the internal investigation may well waive the attorney-client or work-product privileges. See Westinghouse Electric Corp. v. Republic of the Philippines, 951 F.2d 1414 (3rd Cir. 1991); Permian Corp. v. United States, 665 F.2d 1214 (D.C. Cir. 1981); In re: Martin Marietta Corp., 856 F.2d 619, 629 (9th Cir. 1988). But see, In re: Steinhardt Partners, 9 F.3d 230 (2nd Cir. 1993).

B. Duty To Disclose

1. General Rule. As a general rule, businesses and individuals are under no legal obligation to report noncompliance to the

government. But see, 18 U.S.C. § 4 affirmative concealment of and failure to report a federal felony offense is the crime of misprison of a felony.

2. Fifth Amendment. Furthermore, the Fifth Amendment protects individuals from compelled disclosure of incriminating evidence, and therefore a rule requiring individuals to report regulatory noncompliance may be unconstitutional if the regulatory noncompliance is evidence of a crime. The Fifth Amendment does not protect corporations and other fictitious persons.

3. However, under the Health Insurance Portability and Accountability Act of 1996, it is a felony if a provider knowingly and willfully falsifies, conceals, or covers up a material fact (i.e. known overpayment).[5] It is unclear whether a **[mere]** failure to disclose, in contrast with an intentional act to conceal, could be construed as "covering up" a material fact for purposes of this section.[6]

4. Furthermore, the Medicare fraud and abuse statute specifically references the failure of a provider to disclose receipt of an unauthorized benefit payment (i.e., "Known Overpayment). That statute provides, in pertinent part, as follows:

> "Whoever having knowledge of the occurrence of any event affecting his initial or continued right to . . . [a] benefit or payment [from a federal health care program] . . . conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount than is due or when no such benefit or payment is authorized" is punishable by a sentence or up to five years imprisonment and a fine of $250,000 for individuals and $500,000 for corporations.[7]

5. The statute quoted above has not been construed in this context in reported case law or interpreted by Federal regulations and does not provide any procedure for disclosure or to whom the disclosure should be made. The statute also appears to require a provider to

---

[5] 18 U.S.C. ə 1035.
[6] *Covington v. Sisters of the Third Order of St. Dominick of Hanford*, 1995 U.S. App. LEXIS 20370 (9th Cir. 1995).
[7] 42 U.S.C. ə 1320a-7b(a)(3).

disclose receipt of an overpayment even where the cause of the overpayment was a mistake by the government.

6. Finally, the case law construing the United States Civil False Claims Act prior to its amendments in 1986 suggested that an entity could be held liable for failing to disclose and repay a known overpayment. The amendments to the False Claims Act added a specific provision requiring providers who discover overpayments to return the received payments or be subject to civil liability under the False Claims Act.[8]

C. Disclosure to the Carrier or Intermediary

1. Assume that the provider determines after an internal audit that an overpayment was received, and there was no indication of intentional wrongdoing. The disclosure in this instance should be handled as an overpayment refund to the carrier or intermediary. However, this should only occur after the provider is certain of the scope of the problem and that no intentional wrongdoing occurred.

2. The disclosure should be made in writing and should identify:

   (a) the error that caused the overpayment;

   (b) an overpayment estimate with an explanation of the method of calculating the overpayment;

   (c) the period of time reviewed; and

   (d) the corrective action the provider took to remedy the problem, if it was not a government error.

3. The provider returns a check to the intermediary or carrier with the full amount of the overpayment. No penalties or interest need to be included with the refund.

[8] *See, e.g., Covington,* 1995 U.S. App. LEXIS 20370 (citing, *United States v. McLead,* 721 F. 2d 282, 283 (9th Cir. 1983)).

D. False Claims Act Disclosure

1. The False Claims Act ("FCA") gives providers incentives to disclose matters within its scope voluntarily.[9] Those incentives include the following:

   (a) The provider will be required to refund only double damages instead of facing treble damages;

   (b) The provider will not face the per claim penalties otherwise applicable and ranging between $5,000 and $10,000 per claim; and

   (c) The possibility of a defense to Qui Tam actions with respect to the matters disclosed.

2. The disclosure under the FCA must meet certain conditions before the provider can qualify for the incentives listed above. First, the disclosure must be made to the Department of Justice ("DOJ"). Second, the disclosure must be made by the person or entity that violated the FCA. Third, the disclosure must be made within 30 days after the provider first obtains information about the FCA violation.[10]

3. Although the FCA provides benefits for voluntary disclosures, providers also risk criminal liability due to the nature of FCA violations. Therefore, providers must work closely with counsel before making a FCA disclosure.

E. OIG's Provider Self-Disclosure Protocol

1. Introduction

   (a) Replaced the OIG's Voluntary Disclosure Program, which was only available to certain types of providers that operated in five states.

   (b) The Provider Self-Disclosure Protocol (the "Protocol") is open to all types of providers in all 50 states.[11]

---

[9] 31 U.S.C. ə3729 *et seq.*
[10] *Id.*
[11] OIG News Release www.dhhs.gov/progorg/oig/modcomp/distress.pds (October 21, 1998).

(c) The OIG does not guarantee a favorable resolution of the disclosed matter. The OIG merely states that early disclosure "generally benefits" the provider.[12]

(d) The OIG expects the provider to disclose specific information and engage in specific self-evaluative steps relating to the disclosed matter.

(e) The fact that a disclosing provider is already subject to a government inquiry will not automatically preclude a disclosure.

2. Initial Disclosure

(a) When a provider discovers a potential problem that has led to an overpayment, the OIG encourages the provider to submit an "effective disclosure" in writing to the OIG (the "Initial Disclosure").

(b) The Initial Disclosure must include the name, address, provider identification numbers, and tax identification numbers of the disclosing provider. If the provider is an entity that is owned, controlled, or is otherwise part of a system or network, the disclosure must include a description or diagram describing the pertinent relationships and the names and addresses of any related companies.

(c) The provider must state whether, to its knowledge, the matter is under current inquiry by a government agency or contractor. If the provider is under investigation, whether individually or as an organization, the provider must disclose that information to the OIG.

(d) The Initial Disclosure must contain a full description of the nature of the matter being disclosed, including the type of claim, transaction, or other conduct giving rise to the matter. It must also include the names of entities and individuals believed to be implicated and an explanation of their roles in the matter during the relevant periods.

---

[12] Department of Health and Human Services, Office of Inspector General, *Publication of the OIG's Provider Self-Disclosure Protocol* 63 F. R. 58399, 58400 (October 30, 1998). See copy attached.

(e) The Initial Disclosure must describe the type of health care provider implicated and any provider billing numbers associated with the matter disclosed. It must also contain a statement as to why the disclosing provider believes that a violation of federal criminal, civil or administrative law may have occurred.

(f) The provider must certify in the Initial Disclosure that, to the best of the provider's knowledge, the submission contains truthful information and is based on a good faith effort to bring the matter to the government's attention.

3. Internal Investigation

(a) The disclosing provider is expected to conduct an internal investigation and a self-assessment and report its findings to the OIG. The internal review may occur after the provider submits its Initial Disclosure.

(b) The OIG will generally agree, for a reasonable period of time, to forego an investigation of the matter if the provider agrees it will conduct the review in accordance with the OIG's guidelines.

(c) The matter cannot be resolved with the OIG until the provider has completed a comprehensive assessment pursuant to the OIG's guidelines.

(d) The provider must submit a voluntary disclosure report (the "Report"), demonstrating that a full examination of the practice has been conducted.

(e) The Report must contain a written narrative that identifies the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, etc.).

(f) The Report must describe the incident or practice in detail, including how the incident or practice arose and continued.

(g) The Report must identify the divisions, departments, branches or related entities involved.

(h) The Report must identify the impact on, and risks to, health, safety or quality of care.

(i) The Report must identify the period during which the incident or practice occurred.

(j) The Report must identify the corporate officials, employees or agents who knew of, encouraged, or participated in, the incident or practice and any individuals who may have been involved in detecting the matter.

(k) The Report must estimate the monetary impact of the incident or practice upon the Federal health care guidelines, pursuant to the Self-Assessment Guidelines (below).

(l) The Report must also describe how the incident or practice was identified, the entity's efforts to investigate and document the incident or practice, and the chronology of the investigative steps taken in connection with the provider's internal inquiry into the disclosed matter.

(m) The Report must also describe the actions the provider took to stop the inappropriate conduct and any disciplinary action taken against any responsible individuals.

4. Self-Assessment Guidelines

(a) The OIG requires the provider to estimate the monetary impact of the disclosed matter on the Federal health care programs in accordance with its Self-Assessment Guidelines. The OIG will verify the provider's calculation and will look more favorably upon providers who accurately assess the monetary impact.

(b) Providers must conduct a self-assessment that consists of either a review of all the claims effected by the disclosed matter during the relevant period or a statistically valid sample of the claims that can be projected to the population of claims that were affected.

(c) The disclosing provider is encouraged to submit to the OIG a work plan describing the self-assessment process. If necessary, the OIG will provide comments to the provider in a timely manner.

(d) The OIG may choose to interject itself and carry out any activities it deems appropriate at any stage of the review to verify that the self-assessment process is undertaken to its satisfaction.

(e) If the provider's Report is accurate, the OIG will use it in preparing a recommendation to the DOJ for resolution of the provider's False Claims Act or other liability.

(f) The OIG's Self-Assessment Guidelines contains specific criteria for providers in developing their self-assessment process. These guidelines address the selection of the claims to be reviewed, appropriate sample sizes, and the estimation methodologies the providers are to use.

(g) Upon completion of the self-assessment, the disclosing provider must certify to the OIG that, to the best of its knowledge, the report contains truthful information and is based on a good faith effort to assist OIG in its inquiry and verification of the disclosed matter.

5. OIG's Verification

(a) Upon receipt of the provider's report, the OIG will begin verifying the disclosed information.

(b) The extent of the OIG's verification depends on the quality and thoroughness of the internal investigation and the provider's report.

(c) New problems uncovered during the OIG's verification may be treated as new matters outside the provider self-disclosure protocol.

(d) The OIG requires full access to all audit work papers and other documents without the assertion of privileges or limitations on the information produced.

(e) The OIG states that it will not usually request production of written communication subject to the attorney-client privilege. However, if the OIG needs such documents, the OIG states that it will discuss with the provider's counsel ways to gain access to it without requiring a provider to waive any applicable privileges.

6. Payments

(a) Until the OIG has verified the scope and impact of the disclosed matter, it will not accept payments of presumed overpayments by a provider.

(b) The OIG encourages providers to place estimated overpayments in an interest-bearing escrow account until completion of the OIG's inquiry.

(c) While the matter is under OIG inquiry, the provider must refrain from making payment relating to the disclosed matter to the provider's contractors without the OIG's prior consent.

7. Cooperation with the OIG

(a) The OIG expects to receive documents and information from the disclosing provider without the need to resort to compulsory methods.

(b) If a provider fails to work in good faith as determined by the OIG, the OIG will consider that an aggravating factor when it assesses the appropriate resolution of the matter.

(c) Any intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to the DOJ or other Federal agencies for appropriate civil and/or criminal sanctions.

F. Conclusion

Providers that discover potential overpayments or other billing problems may disclose those matters to one or more of several entities. The decision whether to disclose, and if so, to what entity, depends on the totality of the facts and circumstances of the provider's situation. Although voluntary disclosure often brings the provider benefits, such disclosure in certain instances could also bring criminal liability. Therefore, voluntary disclosure decisions should be made only after the provider has received advice of competent counsel.