

INTERNAL INVESTIGATION STRATEGIES IN HEALTHCARE FRAUD & ABUSE MATTERS

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I. INTRODUCTION

Last year, the U.S. Department of Justice (“DOJ”) and U.S. Department Health and Human Services (“HHS”) recovered \$7.2 billion through criminal and civil health care fraud enforcement activities, including a precedent-setting \$3 billion settlement with GlaxoSmith Kline.² DOJ alone initiated over 1,100 new criminal health care fraud investigations in 2012 and convicted over 800 defendants of health care fraud-related crimes during the year.³ These activities resulted in the highest three-year average return on investment since the Health Care Fraud and Abuse (“HCFAC”) Program began 16 years ago with \$7.90 recovered for each dollar spent.⁴

DOJ and HHS stepped up their coordination activities in 2012 by continuing the efforts to strengthen the partnership between Federal, State and local officials, including several leading private health insurance organizations, and other health care fraud groups. The public-private partnership is designed to encourage the sharing of information and best practices among stakeholders to better detect and prevent fraud in health care billing.⁵ Combined with the ever-increasing effectiveness of HHS and DOJ’s joint Health Care Fraud Prevention and Enforcement Action Team (“HEAT”), the environment is ripe for continued focus on health care fraud enforcement making it critical that

compliance officers and in-house counsel understand how to properly handle both internal and governmental investigations.

In today’s healthcare world, even the most ethical organizations are faced with substantial risks while operating in a highly regulated field of ever changing rules. Investigations disrupt operations, impair business initiatives, exhaust resources and expose organizations to negative public relation campaigns. These costs occur even prior to ascertaining whether there will be consequential administrative, civil or criminal liability. By providing an overview of the investigative process, this article is intended to assist compliance officers and counsel so that they may seek to reduce the negative impacts of investigations.

As a preliminary matter, the most important tool for anyone dealing with these issues is personal credibility. Whether you are dealing with the government directly or conducting an internal review with an eye toward potentially addressing the government in the future, establishing personal credibility is key. Compliance officers and counsel who lose credibility internally or with the government will draw added scrutiny to their organizations, whereas individuals who establish credibility may receive the benefit of the doubt. While this may seem obvious, many investigations have

gone astray when those in charge lose the faith of senior management, boards or government agencies.

The first step to building credibility is developing a complete understanding of the investigatory process and the facts at issue. This article provides an overview of that process and addresses some key points where compliance officers and counsel can improve on how they conduct internal investigations. The article further discusses how to respond to subpoenas, search warrants and interview requests. As outlined below, well-conceived and managed internal inquiries are critical for organizations to ameliorate the negative consequences of investigations.

II. THE START OF GOVERNMENTAL INVESTIGATIONS

The consequences of criminal prosecution are so severe that every organization must ensure that they have a plan to address claims of potential criminal wrongdoing before allegations arise. When issues arise—whether through a hotline complaint, internal report, civil subpoena, grand jury subpoena, search warrant or a simple request—organizations and their counsel need to have a basic understanding of the investigatory process and how to communicate with agents and prosecutors.

Governmental investigations typically begin when a source of information, usually an employee or former employee, reports allegations of wrongdoing to a Zone Program Integrity

Contractor (“ZPIC”), Medicare Administrative Contractor (“MAC”), HHS Office of Inspector General (“OIG”), Federal Bureau of Investigations (“FBI”) or Medicaid Fraud Control Unit (“MFCU”). More recently under the direction of HEAT, investigations are being started when anomalies in claims are detected by HHS-OIG and FBI agents working with a Medicare Fraud Strike Force (“MFSF”) and through an increased focus on data-mining and sharing among various government agencies. And while sources may be relators in a *qui tam* case brought under the FCA, the investigations regardless of how they originate generally take the same form. Other agencies that may join in healthcare fraud investigations include the Internal Revenue Service (“IRS”), the Postal Inspection Service, Department of Defense (“DOD”), Veterans Administration (“VA”), Railroad Retirement Commission and State Insurance Departments (“DOI”).

In most cases, the first sign of an investigation is agent contact with a current or former employee or a letter requesting information. These initial contacts are often followed by administrative, civil or criminal subpoenas. Less often, organizations learn of the commencement of an investigation during the execution of a search warrant. MFSFs have made increased use of this tool as of late, however, as evidenced by a single-day coordinated takedown across seven cities in May 2012 that resulted in over 100 individual arrests and 20 executed search warrants.⁶ Whatever the initiating government contact, organizations need to quickly ascertain

their status in the investigation—target, subject or witness. Organizations also must understand their rights and those of their employees.

Regardless of the origin of the investigation, or the depth of the organization's potential involvement in the matter, the first priority should always be to get the facts. During the initial stages of an investigation, the organization has a unique opportunity to develop a relationship with the investigating agency. Early on, the government proceeds with limited information while it collects additional information. As the investigation progresses, the government seeks to confirm its perceived notion of the suspected violation. When organizations fully understand the facts, they can influence the way the government perceives the case by guiding investigators through documents and witnesses. Whether the organization is contesting the allegations or not, organizations must seek to understand how the government views the allegations.

A. Requests

Organizations sometimes learn of investigations from employees who report that government agents approached them. In such situations, counsel should talk with the employees and attempt to ascertain the nature of the government's investigation. Thereafter, the organization must decide how to prepare other employees for similar interviews. Since a witness is the property of neither the government nor the organization, both sides have equal access to the witness.⁷ However, this

has little practical meaning if employees are unaware of their options when confronted by investigators. Thus, it is appropriate, for an organization to apprise its employees of their rights and obligations should they be contacted by agents and asked to submit to an interview.

Organizations should assure individual employees that they are free to answer questions from government agents and that all answers must be truthful if they elect to answer questions. Also, organizations are free to explain the benefits of declining an interview until the employee has had an opportunity to meet with counsel. Among other benefits, an individual who meets first with counsel will better understand the government's methods and objectives. At a minimum, organizations should request that individual employees who are approached by investigators request the agent's background information, including the agent's name, agency and phone number. All contacts should be handled immediately and as confidentially as possible. All government agents must be treated seriously and accorded respect. Agents and prosecutors who sense obstructive conduct will respond by escalating the investigation, and may open new investigations into additional criminal conduct such as obstruction of justice.

Individuals may elect to be represented by counsel during the interview. For those individuals, the organization must determine whether the employee requires separate counsel and whether the organization will assume the cost of such representation.

These determinations are generally best left to counsel who have access to the organization's governing documents and are aware of other potential conflict and jurisdictional issues. Counsel for the organization must always keep in mind the ethical rules and not cross the line of representing an individual in a personal capacity. As such, counsel for the organization must make clear to individuals that they represent the organization.

The manner in which employees are apprised of their rights necessarily will vary depending on the circumstances of the case, including the number of employees involved, their positions and locations, and the likelihood that the government may contact them before they can be interviewed by the organization. Organizations should consult counsel regarding the preparation of a contact letter or before initiating any other contact.

B. Subpoenas

After the government's initial contact, organizations may receive a subpoena. Subpoenas can be administrative, civil and/or criminal. Upon receipt of any subpoena, organizations should refer the request to counsel to review the validity of the subpoena. After reviewing the subpoena, counsel must ensure that responsive communications are retained. Counsel may issue a memorandum or "hold notice" to employees describing the request. This memorandum should explain the subpoena in plain English – not legalese, what documents should be

retained, who will be collecting the documents, and contain instructions on how to collect documents for those participating in the collection.

Counsel evaluating a subpoena also should have their client detail the state of its records and its ability to comply with the request. As soon as the organization supplies this information, counsel should contact the government to discuss compliance issues. Given the nature of the subpoenaed material, counsel may seek to limit production based on overbroad requests, requests for privileged material, vague terms in requests, or expansive time periods covered by requests. Typically, counsel for the government will entertain reasonable requests to narrow subpoenas. If compliance issues remain unresolved, organizations must decide whether to pursue a motion to quash the subpoena. Rarely do issues exist in subpoenas that the government will not be able to cure, so it is generally unadvisable to move to quash a subpoena without exhausting all avenues with the government.

C. Search Warrants

The government will use search warrants when it believes there is a substantial risk that evidence will be destroyed. After it establishes by *ex parte* presentation to a court that there is probable cause to believe that a crime has been committed, the government will execute a search to seize relevant evidence. The government rarely uses search warrants in healthcare matters that involve organizations that are in the business of providing real care.

Search warrants are invasive, disrupt operations, can jeopardize patient care and create employee anxiety. During any search, employees should contact counsel or a designated employee immediately. If served with a warrant, organization employees must inspect the warrant for facial sufficiency (location, time, date and scope) and comply with its terms. It is also advisable that non-essential employees (those not involved in patient care) be sent home immediately. Having employees leave the facility will assure that their actions are not misinterpreted as interfering with the search. Further, limiting the number of employees at the search will minimize interviews and assure that employees do not expand the scope of the search by consent. To the extent practicable, communication with the agent in charge of the search is advisable to ascertain the nature of the allegations. Counsel also should seek a copy of the affidavit filed in support of the warrant.

Warrants permit the government to seize original documents. To safeguard an organization's interests, counsel should request copies of items seized and/or the return of critical documents. At a minimum, the senior person on the scene should keep track of the areas searched, questions asked and items taken. One consideration is whether to assist the agents in locating the items listed in the warrant. In most instances, where counsel for an organization assists the agents in locating the items listed in the warrant, the process proceeds at a faster pace and reduced scope. At the end of the search, counsel should request an inventory and

attempt to assure that the inventory fully describes the items seized.

II. CONDUCTING INTERNAL INVESTIGATIONS

The initial decision that must be made by in-house counsel and compliance officers upon learning of government involvement or a serious issue is whether to perform an internal investigation. Counsel should perform a thorough investigation if the organization may be involved in the alleged misconduct or may have direct exposure (criminal, civil or administrative), or when the government's claims may involve senior management, board members or employed providers.

After the government's initial contact, counsel must learn and understand the allegations, the nature of the investigation and the organization's exposure before recommending action. To the extent possible, counsel should ask the government or source of information to describe the role of the organization and its key employees. If the matter is a government investigation, the organization should ask whether they are a target or subject of a criminal investigation. As long as the inquiry is a genuine attempt to understand the investigation, the government should welcome the discussion. While the government might not always accommodate the request, if done in a professional manner, there is no harm in seeking information. Having information from the government can assist in designing and implementing a thorough internal investigation plan. Where there is an

active criminal investigation, organizations should not conduct an internal review until the parameters of the review have been discussed with agents and prosecutors, as it might compromise on-going law enforcement activities.

All internal investigations must be calibrated to the nature of the allegations in order to determine what happened, who was involved and why it occurred. Understanding why individuals acted as they did is, in many ways, the most subtle and important goal of the internal investigation. In some circumstances, the internal investigation itself ultimately may serve as an indication of corporate responsibility and good citizenship. DOJ's Principles of Federal Prosecution of Business Organizations cites a "corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents" as one of nine factors to consider in deciding whether to charge a corporation with a criminal violation.⁸ Under every articulated standard, however, self-examination and a determination if wrongdoing occurred is the predicate to appropriate corrective action.

A. Who Should Conduct the Internal Investigation

As a general rule, counsel should conduct or supervise the investigation. Legal questions related to whether the conduct at issue constitutes a violation are the heart of any investigation. Counsel must identify and resolve these issues based upon an analysis of the facts. Given DOJ's revised corporate

guidelines, which counsel that "a corporation need not disclose and prosecutors may not request the disclosure of [legal advice and attorney work product] as a condition for the corporation's eligibility to receive cooperation credit,"⁹ organizations may have more comfort that DOJ will accord the attorney-client privilege its due respect.¹⁰ Thus, the attorney-client privilege may be asserted to protect certain communications, and the work product doctrine likewise will pertain to materials generated there under, only if the investigation is conducted by, or at the direction of, attorneys for the company.¹¹

Whether in-house or outside counsel should be responsible for conducting the investigation is subject to a number of general considerations. In-house counsel may be better acquainted with the company's history, structure, procedures and operations. Company employees are more likely to be open with in-house counsel because employees are more familiar with them. Unfortunately, in-house counsel may viewed by the government as lacking independence due to their status within the management structure. This is true particularly where alleged wrongdoing implicates an individual who has regular contact with in-house counsel. In these situations, it is advisable to seek outside counsel.

Another consideration is that it may be more difficult for in-house counsel to establish and maintain privilege because they are frequently called upon to provide business advice. This problem is exacerbated when information obtained in the internal

investigation is shared by in-house counsel with auditors, accountants, underwriters and corporate officials not involved in defending the organization.¹² The primary concern with waiver is that it could extend to civil litigation.¹³

Outside counsel, because they are less familiar with the company's activities and personnel, may be more objective in assessing practices. The judgment of outside counsel experienced in defending government investigations also may be a valuable asset to a company faced with allegations of wrongdoing. Similarly, outside counsel may be better acquainted with the subtle problems that often arise in the course of internal investigations. For example, they may be better able to avoid unfounded allegations of witness interference and obstruction of justice. Further, where the government perceives a conflict between the interests of a company's management and the interests of its employees, outside counsel also may have advantages in dealing with government investigators and prosecutors. The government is especially sensitive to the influence that management exercises over employees, and this tends to color the government's view of the conduct of in-house counsel.

In light of the foregoing considerations, it often is most effective for an internal investigation to be conducted by outside counsel, in close coordination with in-house counsel.

B. Documents & Witnesses

The two principal components of an internal investigation are: (i) an analysis of relevant documents; and (ii) interviews of employees who may be able to provide relevant information. Generally, it is preferable to review documents prior to commencing interviews. The documents are a source of the identities of the individuals who will need to be interviewed as the internal investigation progresses. The government also identifies the employees it would like to interview based upon the documents. Further, the documents often raise questions which can be answered only through interviews of employees. The documents also may help refresh the recollections of the individuals being interviewed and avoid mistaken responses that may throw the internal investigation off course.

When interviewing employees, they must be informed of the purpose of the interview. Ordinarily, this would include advising each interviewee: (i) that the government is conducting an investigation; (ii) of the nature of the problem being investigated; (iii) that counsel has been retained to provide advice to the organization; and (iv) that the interview is necessary in order for counsel to obtain the information needed to provide appropriate advice.¹⁴ Of course, the employee should be advised that the interviewer is not counsel to the employee and that any privilege belongs to the organization, who may choose to waive it. In some circumstances, although it may cause the employee to be less forthcoming, it is prudent to advise the employee

affirmatively that the substance of the interview may be disclosed to company officials or the government.

Where it appears that the interests of the company may be adverse to those of an employee, clarity as to the lawyer's role is critical, as set forth in Rule 1.13 of the *ABA Model Rules of Professional Conduct* and its Comments. During interviews, it is important to avoid statements that might be misconstrued as an attempt to influence the witness's testimony. Therefore, characterizations of an organization's position on issues, or of the testimony of other witnesses, should be avoided.

After any interview, it should be reduced to a memorandum. As the organization may ultimately decide to waive the attorney-client privilege and work product protection, counsel should draft fact-based summaries without opinion. With regard to the potential of waiver, former director of the Executive Office of United States Attorneys ("EOUSA") Mary Beth Buchanan previously noted that "[t]o avoid any such disclosure unnecessarily, experienced attorneys will refrain from including mental impressions and strategy in their notes of witness interviews."¹⁵

C. Determining Who Needs Counsel

Individual conduct is always at issue in government investigations. As such, some individuals may need separate legal counsel to advise them of their rights and obligations. Although it is difficult to generalize, where an

organization is the subject of a criminal investigation, there often is a serious potential for the existence of a conflict between it and its employees. For example, an employee may have taken a questioned action based upon information or direction received from a supervisor. Even if contrary to company policy, the action would in all likelihood be attributable to the company, and the company could be held vicariously liable if the individuals involved possessed the requisite knowledge and intent. In such a situation, the interests of the company, the supervisor and the employee may vary. Accordingly, counsel for the company should refrain from saying anything that may be construed as legal advice to a witness.

Where an individual has committed a crime, the corporation has an interest in punishing and disclosing the conduct. EOUSA Director Buchanan previously advised that "a zero tolerance approach to employee crime is integral to the organizational culture of a good corporate citizen and can be based on rewards as well as punitive action Employees who have committed crimes using the corporate structure, however, cannot expect protection from their corporate employer."¹⁶

D. Finalizing Findings

After counsel has reviewed the documents and interviewed those knowledgeable about the matter, it is helpful to prepare a memorandum that: (i) summarizes the facts developed through the internal investigation; (ii) analyzes applicable legal principles; (iii) identifies any weaknesses in the company's practices or procedures; (iv)

outlines the arguments against criminal prosecution or administrative sanctions; and (v) recommends any corrective actions or other measures which would improve operations and enhance the company's defenses. Most cases involving suspected fraud are complex, and the significance of certain facts can be difficult to grasp unless distilled in a written analysis. After this is complete, the organization may evaluate the conduct and options. The final decisional process is heavily fact specific and must be made with the advice of experienced counsel.

While an internal investigation conducted after an organization has been contacted by the government is different from an investigation conducted prior to the government's involvement, the investigation's findings may trigger disclosure requirements.¹⁷ For example, the Centers for Medicare and Medicaid Services ("CMS") requires certain disclosures for Medicare Advantage and Medicaid managed care providers, and many state laws require nursing homes to report all alleged incidents of abuse, mistreatment, neglect, and misappropriation of resident property. Such reports to state officials may implicate a false claims analysis should the quality of care be so low that DOJ considers program payments excessive. Additionally, for certain types of corporations, if evidence of illegality or misconduct is uncovered in the course of the investigation, disclosure may be required under the securities laws.¹⁸ Further, the Sarbanes-Oxley Act requires that the corporate officer signing a company's periodic report certify that any fraud which involves management (or other

employees who have a significant role in the company's internal controls), whether or not material, be disclosed to the auditors and the audit committee.¹⁹

E. Voluntary Disclosure

Even where mandatory disclosure is not implicated, organizations conducting internal investigations prior to government involvement still may face the complex decision of whether to make a voluntary disclosure under the OIG's self disclosure protocol ("SDP") or CMS's Self-Referral Disclosure Protocol ("SRDP"), which saw increased utilization in 2012. Self-disclosure may be appropriate in certain cases, but organizations contemplating this avenue should not proceed before undergoing thorough investigation, evaluation and judgment, and seeking the assistance of legal counsel.

The OIG protocol is intended for matters that may involve potential fraud against government healthcare programs, and disclosures should only follow a reasonable assessment by the organization that certain matters are potentially violative of criminal, civil or administrative laws.²⁰ The protocol is not intended to cover mere inadvertent billing mistakes or Medicare overpayments, which instead should be addressed through the claims reconciliation process.²¹

Several considerations may motivate the decision to self-disclose, and organizations should carefully weigh the benefits and risks associated with following the SDP. To the OIG, disclosing in good faith may signal that an organization embraces a culture of

compliance and is committed to interacting with federal healthcare programs with integrity. Thus, benefits may include the potential for increased leniency signaled by the OIG forgoing its exclusion power or basing a settlement offer at the lower end of the civil monetary penalty (“CMP”) range.²² Following the protocol may avoid the presumptive imposition of a corporate integrity agreement (“CIA”) that can significantly burden an organization with years of costly oversight obligations.²³ Less quantifiable, self-disclosure also may give organizations the opportunity to gain control over the situation and cast the matter in a light so as to avoid government misunderstanding.

Equally important to consider, however, are the risks associated with self-disclosure. Notably, OIG makes no guarantee of leniency, benefit or immunity to those that take advantage of the SDP. Resolving issues through the SDP also may be expensive, time consuming and disruptive. At times, disclosure may trigger a new investigation or expand an existing investigation into new territory by OIG or other agencies. Further, the disclosure to OIG of internal investigation reports and underlying documentation may create waiver issues related to the attorney-client privilege and work product protections, creating potentially significant issues in any subsequent civil litigation.

When used appropriately, the SDP can be an effective tool for mitigating risk associated with potential fraud and abuse violations, but the decision to pursue the self-disclosure

avenue should benefit from the advice of legal counsel and include careful weighing of the nature of the wrongdoing against potential benefits of disclosure. OIG also announced last year that it intended to update the SDP and solicited suggestions from the public on potential revisions.²⁴ Companies considering a disclosure under the SDP should keep abreast of these anticipated changes and incorporate any revised guidance in their self-disclosure analyses.

F. Cooperation

If criminal conduct is discovered during an investigation, an organization must decide how to proceed. This determination is case specific and will be based upon potential exposure. Where the conduct poses the risk of corporate indictment, organizations have little choice but to cooperate given the risk of exclusion. This decision, however, must not be taken lightly. Only full cooperation is worth undertaking, and attempts at partial cooperation may be worse than none at all. Given the “no cooperation is better than incomplete cooperation” standard, it is imperative that counsel conducting the investigation thoroughly examine key documents and witnesses and make sure that the facts are known.

The decision to cooperate will impact how the internal investigation report is assembled. Once an organization has made a decision to cooperate with the government, 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 privilege and work product protections.

G. Preparation for Interviews

Whether a corporation decides to cooperate or not, the government typically will conduct witness interviews. Even when presented with a comprehensive internal investigation report and full interview notes, the government will seek to confirm the report's findings. In addition to informal requests for interviews, the government's use of civil investigative demands ("CIDs") has greatly increased with the adoption of new rules in 2010 allowing the Attorney General to delegate authority to issue CIDs to individual United States Attorneys and the Assistant Attorney General for the Civil Division. For organizations subject to healthcare fraud investigations, the new rule has a significant impact, forcing organizations to move even more swiftly in conducting its internal investigation and requiring prompt production of witnesses and documents for government inspection. For everyone who gets called as a witness, careful preparation is necessary.

An individual who has not received preparation about the government interview, CID or grand jury process may inadvertently make statements that confuse issues or create the impression of improprieties that do not exist. This is especially true when witnesses are questioned by agents with a preconceived theory of the case. Moreover, if unprepared, a witness may unintentionally make statements that contain inaccuracies that later can

create credibility concerns or give rise to charges of perjury. Nevertheless, preparation of individuals by counsel in advance of government interviews must be free from undue influence and misleading conduct. Whether prepared by counsel for the company or separate counsel, individuals should be advised of the importance of telling the truth. Counsel must explain the importance of answering questions truthfully and with complete candor.

IV. CONCLUSION

When faced with a healthcare fraud investigation, organizations must have a plan to effectively ascertain the relevant facts and develop a strategy of open communication with the government. Although organizations and the government might not always agree on the appropriate outcome, it is possible to reach workable compromises if the parties communicate openly. For compliance officers and counsel to have credibility in its interactions with the government, they must understand the facts, the investigation and the potential exposure. Undertaking internal investigations that are appropriately planned and executed help prepare organizations to address government concerns and allegations. It is impossible for an organization's management or board to chart an appropriate course in the face of potential wrongdoing without sound legal and compliance advice. In conclusion, all well-grounded action plans to protect organizational interests depend upon a command of the facts and an ability to persuasively communicate the facts.

¹ I would like to thank *Jessica Talati* for her assistance in the preparation of this article. Ms. Talati is an associate in the White Collar Defense Group of Arnold & Porter LLP's Washington, DC office. Since 2009, Ms. Talati has represented health care providers and pharmaceutical companies in a wide variety of fraud and abuse matters. Ms. Talati is an honors graduate of Northwestern University School of Law where she served as Executive Editor of the *Northwestern Journal of Technology and Intellectual Property*.

² "The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 2012," available at <http://oig.hhs.gov/reports-and-publications/hcfac/index.asp>.

³ *Id.*

⁴ *Id.*

⁵ Press Release, Health and Human Services, Obama Administration Announces Ground-Breaking Public-Private Partnership To Prevent Health Care Fraud, (July 26, 2012), available at <http://www.hhs.gov/news/press/2012pres/07/20120726a.html>.

⁶ Press Release, Medicare Fraud Strike Force Charges 107 Individuals for Approximately \$452 Million in False Billing (May 2, 2012), available at <http://www.justice.gov/opa/pr/2012/May/12-ag-568.html>.

⁷ See *United States v. Medina*, 992 F.2d 573, 579 (6th Cir. 1993); *United States v.*

Matlock, 491 F.2d 504, 506 (6th Cir. 1974); *Gregory v. United States*, 369 F.2d 185, 188 (D.C. Cir. 1966).

⁸ Principles of Federal Prosecution of Business Organizations, 9-28.300 "Factors To Be Considered," at 4, available at <http://www.justice.gov/opa/documents/corp-charging-guidelines.pdf> (last accessed April 2, 2013) [hereinafter "Filip Memo"].

⁹ *Id.* at 12.

¹⁰ Instead of waiver, DOJ's consideration of corporate cooperation now places greater emphasis on the disclosure to the government of all relevant facts. *Id.* at 9-13.

¹¹ See generally *Upjohn Co. v. United States*, 449 U.S. 383 (1981); *Gruss v. Zwirn*, 276 F.R.D. 115 (S.D.N.Y. 2011) (discussing work product protection in the context of internal investigations).

¹² See, e.g., *id.*; *John Doe Corp. v. United States*, 675 F.2d 482 (2d Cir. 1982); *In re Wilkie, Farr & Gallagher*, 1997 U.S. Dist. LEXIS 2927 (S.D.N.Y. Mar. 14, 1997).

¹³ *In re Columbia/HCA Healthcare Corp. Billing Practices Litig.*, 293 F.3d 289 (6th Cir. 2002) (holding that the company's disclosure of internal audits to DOJ during a fraud investigation waived privilege); *In re Subpoena Duces Tecum*, 738 F.2d 1367 (D.C. Cir. 1984) (holding that the disclosure of an internal investigation report and underlying documents to SEC waived privilege); *In re Initial Public Offering Sec. Litig.*, 249 F.R.D. 457 (S.D.N.Y.

2008) (holding attorney work product privilege was waived by disclosure to United States Attorney's Office and SEC).

¹⁴ See, e.g., *Upjohn*, 449 U.S. at 394 (discussing protected communications by corporate counsel with company employees).

¹⁵ Mary Beth Buchanan, *Effective Cooperation by Business Organizations and the Impact of Privilege Waivers*, 39 Wake Forest L. Rev. 587, 596 (2004) (citing Deputy Attorney General James B. Comey's remarks to the ABA 14th Annual Institute on Health Care Fraud (May 13, 2004)).

¹⁶ *Id.* at 599.

¹⁷ See 42 U.S.C. § 1320a-7b(a)(3) (2000) (obligating healthcare providers to report known fraud).

¹⁸ See, e.g., Section 10A of the Exchange Act, 15 U.S.C. § 78j-1 (2010); *In the Matter of W.R. Grace & Co.*, Exchange Act Release No. 39157, 1997 SEC Lexis 2038 (Sept. 30, 1997).

¹⁹ 18 U.S.C. § 1350 (2000); 17 C.F.R. § 240.13a-14 (2002).

²⁰ Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,400 (Oct. 30, 1998).

²¹ *Id.*

²² Open Letter to Health Care Providers, April 24, 2006, *available at* [https://oig.hhs.gov/fraud/docs/openletters/OpenLetter to Providers 2006.pdf](https://oig.hhs.gov/fraud/docs/openletters/OpenLetter%20to%20Providers%202006.pdf) (last accessed April 2, 2013).

²³ *Id.*; see also Open Letter to Health Care Providers, April 15, 2008, *available at* <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf> (last accessed April 2, 2013) (reaffirming its April 24, 2006 statements regarding setting liability at the lower range of the damages continuum and presumption in favor of not requiring a compliance agreement).

²⁴ See Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol, 77 Fed. Reg. 36281 (June 18, 2012).