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Current Trends in Voluntary Disclosure Cases

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To disclose or not to disclose, that is the question...

- Questions to ask in determining whether to self-disclose
  - Has there been a violation of law, regulation, rule or guidance?
  - Do you have federal health care funds to which you are not entitled?
    - If so, how much?
  - Was the conduct leading to the violation or receipt of federal money reckless or intentional?
    - Was it merely documentation?
    - Did it involve quality of care?
  - Are you under a CIA?
  - Are you vulnerable to a potential whistleblower?
  - Is this a hot area?
    - On the OIG work plan?
    - Area of great publicity or interest?

To disclose or not to disclose, that is the question...

- Factors to consider when deciding whether to disclose

Pros	Cons
Piece of mind	Point of no return
Good Corporate Citizen	Other issues exposed
Single damages?	Referral to OIG/DOJ?
No CIA or CCA?	State and private entities?
No exclusion	Loss of control

Trend: Self-Disclosure fosters reduced CIA requirements

- OIG conducted and informal survey of CIA negotiations and the ultimate CIA terms and concluded that:

"Significant and appropriate modifications are being made to CIAs with health care providers that have established compliance programs and make disclosures of misconduct to the government"

See: Self-Disclosure of Provider Misconduct: Assessment of CIA Modifications, http://oig.hhs.gov/fraud/cia/docs/assessment.htm

Trend: Self-Disclosure fosters reduced CIA requirements

- OIG's study follows-up on the IG's March 9, 2000 open letter stating that:

  The best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program:

  – identifies problematic conduct,
  – takes appropriate steps to remedy the conduct and prevent it from recurring, and
  – Makes a full and timely disclosure of the misconduct to the appropriate authorities

Trend: Self-Disclosure fosters reduced CIA requirements

- OIG open letter further stated that:

  – More deference would be given to health care providers that voluntarily self-disclosed misconduct, and

  – Under certain circumstances, might not even require a CIA

Trend: Self-Disclosure fosters reduced CIA requirements

- The recent OIG study found that a CIA was generally required to resolve self-reported misconduct.
- So what is the benefit of self-reporting if getting a CIA anyway?
- The OIG reported that, where there was objective evidence of a comprehensive compliance program, the OIG made two significant CIA modifications:
  - A reduction in the term of the CIA from 5 years to 3 years
  - A reduction in the role of the IRO where the provider demonstrated an established system of internal audits

Trend: Self-Disclosure fosters reduced CIA requirements

- Examples demonstrating how the OIG weighs certain factors
  - No CIA where fraud was self-disclosed and conduct was under previous management
  - No CIA where, as part of a pre-existing compliance program, a routine internal audit disclosed that teaching hospital had insufficient documentation for claims to federal health care programs
  - Where one of several non-profit affiliates identified inappropriate mammography codes, no CIA was required because:
    - Voluntarily self-disclosed the issue
    - The misconduct was “isolated”
    - The damage to the government were “relatively small”
    - The hospital had a pre-existing compliance program

Trend: Self-Disclosure fosters reduced CIA requirements

- Other examples provided similar examples where the hospitals were only given 3 year CIAs and were allowed to proceed with out an IRO because:
  - Voluntarily self-disclosed
  - The provider had a pre-existing compliance program
  - Cooperated fully with the government
    - Privilege waiver?

Trend: Self-Disclosure fosters reduced CIA requirements

- Caveat: these examples **cannot** be relied upon as precedents for future CIA resolutions.
- Why not?
  - The examples are not all inclusive of all the factors considered in the negotiations
  - Each case has unique litigation risks and case-specific facts

Trend: Self-Disclosure fosters reduced CIA requirements

- Take away: In addition to arguing that you have a robust compliance program that identified this issue and that you have voluntarily disclosed this problem and have fully cooperated with the government . . .
- Don't forget to argue the merits of your case
  - Litigation risk-unique facts or proof problems?
  - Isolated issue?
  - Relatively small damages?
  - Non-profit, "mission hospital", ability to pay issues?

Trend: Self-Disclosure fosters reduced CIA requirements

- Conclusion
- A provider is often able to:
  - Limit the scope of a CIA
  - Reduce the cost of a CIA
    - Shorter term
    - Less onerous oversight
- In some cases a CIA can be avoided altogether

Trend: Stark and Kickback Resolutions Limited to Overpayment

- In April of 2006 the IG issued an open letter announcing a new self-disclosure initiative designed to provide an incentive to increase the number of self-disclosures by:
  - Providing new clarity as to what types of violations the OIG was interested in to inviting health care providers
    - Stark and kickback cases such as "sweetheart" office leases
  - Providing financial incentives
    - Reduced or no CIAs
    - Damages limited to FMC overpayments as opposed to the disgorgement of entire referred billing

Trend: Stark and Kickback Resolutions Limited to Overpayment

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

An Open Letter to Health Care Providers

April 24, 2006

Protocol (SDP). I am also announcing an initiative that promotes the use of the SDP to resolve civil monetary penalty (CMP) liability under the physician self-referral and anti-kickback statutes for financial arrangements between hospitals and physicians.

In addition to working with our law enforcement partners to sanction companies and individuals who violate the law, OIG also commits substantial resources to promote voluntary compliance by the health care industry. Our guidance to the industry, in the form of Advisory Opinions, Special Fraud Alerts, Special Advisory Bulletins, and Compliance Program Guidance, offers substantive assistance to program participants committed to promoting ethical and lawful conduct in their organizations. Examples of recent guidance include a Special Advisory Bulletin concerning patient assistance programs for Medicare Part D enrollees, and a supplemental

[redacted]. For those providers that demonstrate the requisite level of trustworthiness and that also have in place, or are willing to develop, an effective compliance program, OIG will waive its exclusion authority concurrent with resolution of monetary liability under the False Claims Act and the CMP Law. Typically, these settlements include an integrity agreement between OIG and the provider.

Effective compliance systems are key to strengthening the integrity of the health care system. OIG integrity agreements have been a catalyst for change in corporate culture, and can result in the development of comprehensive internal control systems. Our communications with providers during the course of our compliance monitoring efforts have also enhanced compliance within their organizations.

While we are committed to working collaboratively with providers operating under integrity agreements, some providers fail to demonstrate a commitment to compliance even while operating under such agreements. Integrity agreements typically include contractual remedies

Trend: Stark and Kickback Resolutions Limited to Overpayment

for breach of the agreement, including stipulated penalties and exclusion from Federal health care programs. Since 1999, OIG has imposed stipulated penalties totaling about $300,000 in 21 cases where providers have failed to meet explicit requirements of their integrity agreements. In a recent case involving repeated and flagrant violations of a CIA, we excluded a hospital.

The OIG's November 2000 "Open Letter to Health Care Providers" continues to guide decisions

In appropriate cases, we have agreed to reduce the obligation on providers settling health care fraud matters by entering into Certification of Compliance Agreements (CCAs), rather than more extensive CIAs. CCAs require providers to certify that they will continue to operate their existing compliance programs for a fixed term, typically 3 years, rather than enter into a more extensive CIA with a 5-year term. CCAs do not require independent review organizations to conduct or verify audits or claims reviews.

OIG has heard from hospitals that, through their compliance programs, they are discovering improper arrangements under the physician self-referral law (42 U.S.C. § 1395nn) and are

OIG has the authority to impose CMPs of up to $15,000 for each service billed in knowing violation of the physician self-referral law, and assessments of up to 3 times the amount claimed for such services (see 42 U.S.C. § 1395nn(g)(3)). Hospitals and physicians also have potential liability for these arrangements under OIG's anti-kickback CMP (see 42 U.S.C. § 1320a-7a(a)(7)), which authorizes a penalty of $50,000 for each kickback, plus an assessment of not more than 3 times the total amount of remuneration offered, paid, solicited, or received. In addition to CMPs, OIG may also seek exclusion under these authorities.

OIG's CMP authorities. It is important to stress that OIG's agreement to resolve an SDP matter is not binding upon DOJ.

The initiative is limited to matters that, in the provider's reasonable assessment, involve conduct that subjects the provider to CMP liability under the OIG's physician self-referral and anti-kickback authorities—in particular, situations involving a financial benefit knowingly conferred

Trend: Stark and Kickback Resolutions Limited to Overpayment

by a hospital upon one or more physicians. The financial benefit conferred upon a physician

CMP damages calculation for physician self-referral violations is based on the number and dollar value of improper claims, while the CMP damages calculation for kickbacks is based on the number and dollar value of improper payments or remuneration. Subject to the facts and circumstances of the case, OIG will generally settle SDP matters for an amount near the lower end of this continuum, i.e., a multiplier of the value of the financial benefit conferred by the hospital upon the physician(s).

A provider's participation in the SDP is contingent upon full cooperation and complete disclosure of the facts and circumstances surrounding the violation. Providers will be removed from participation in the initiative unless they disclose in good faith and timely perform the required self-assessment, including quantifying the financial benefits conferred upon the physician(s) and quantifying the full amount of the overpayment. The degree of the provider's cooperation is considered when determining the appropriate terms of an administrative settlement. OIG will also consider the provider's existing compliance program when evaluating whether a CIA, CCA, or no additional compliance measures will be required.

Trend: Stark and Kickback Resolutions Limited to Overpayment

- This is a significant benefit as compared to the huge statutory exposure of 3 times the amount received for the referred services under Stark.
- Has this open letter generated the desired disclosures?
- Has it worked?

U.S. Department of Justice

Medical Center brought this ma[illegible]ent's attention in the Spring of 2006, when it acknowledged paying abo[illegible]c doctors' office in St. Albans in exchange for the doctors providing [illegible]in their office in which the hospital provided x-ray services to the doctors' patients. Because the hospital was paying the doctors more than t[illegible]ket would normally justify, the anti-kickback laws were implicated.

In addition to bringing the matter to the Government's attention, the hospital thereafter cooperated with the Government's investigation into the arrangement. United States Attorney [illegible] complimented the hospital on its approach to this issue, noting that such self-disclosure was evidence of the hospital's good faith in trying to address and correct its past mistakes, factors that weighed very much in the hospital's favor and the United States' decision to resolve the matter without litigation.

The hospital's potential liability was significant. In addition to penalties, it potentially could have been required to pay back up to three times the amount it collected from federal health care programs for care provided to patients referred by the orthopedic practice. Pursuant to the agreement, the hospital has paid the United States $30,000 to resolve its potential liability.

Continuing Self-Disclosure Issues

- False Claims Act Releases

- Providers may be more willing to disclose potential compliance issues if they could get a FCA release
- Government has taken the position that if it is persuaded by the provider that there was not false claims, then it will not provide a False claims Release
- This leaves Good Corporate Citizen Vulnerable
  - Need Qui tam protection
  - Even if government resolves for single damages the relator can still sue under the FCA

Continuing Self-Disclosure Issues

- Double Damages Standard

- The FCA requires not less than double damages in cases of timely voluntary self-disclosures.
  - Only in cases brought to trial through verdict
- Can there be more flexibility on damage multiplier for otherwise good corporate citizens who voluntarily self-disclose misconduct pursuant to a pre-existing compliance program?
- If so, there would be more incentive to come forward with potential instances of misconduct

Continuing Self-Disclosure Issues

- Public Disclosure Bar to Potential Qui Tam Relators
- Is self-disclosure to the FI considered a public disclosure barring a relator who is not an “original source?”
- Is self-disclosure to the DOJ and/or the OIG considered a public disclosure barring a a relator who is not an “original source?”
- If not, then there is a disincentive to self-disclose.

Trends in Self-Disclosure

- Questions?
- Thank you
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An Open Letter to Health Care Providers
March 9, 2000

Three years ago, I wrote an open letter to health care providers, inviting them to join me in a national campaign to eliminate fraud and abuse from the Federal health care programs. I suggested an ambitious agenda that included crafting compliance guidance for health care sectors, designing an effective mechanism to promote self-disclosure of improper conduct, and providing greater awareness of the sanctions that may be imposed on a provider that has engaged in fraud or abuse. By collaborating in our efforts to reduce health care fraud, it was my view that we could serve our common interests of protecting the financial integrity of the Federal health care programs and their beneficiaries, some of our most vulnerable citizens.

Due in large part to strong industry support, I am pleased to report that substantial progress has been made in fulfilling the campaign's objectives. I would like to share with you some of the successes that we have accomplished together and describe new policies the Office of Inspector General (OIG) is implementing to encourage provider self-disclosure. First, three years ago the OIG began producing specific compliance program guidance for segments of the health care industry. These voluntary guidances reflect our suggestions on how providers can design internal controls to monitor adherence with applicable statutes, regulations and program requirements.

To date, we have issued seven compliance program guidances, each reflecting extensive input from industry representatives and compliance officers, as well as our law enforcement partners. These guidances are directed at the hospital industry, home health agencies, clinical laboratories, third-party billers, the durable medical equipment, prosthetics, orthotics and supply industry, hospice providers, and Medicare+Choice organizations. The next guidance to be issued will address compliance measures in the nursing home industry. These voluntary guidances have contributed to a movement in the health care industry to reduce potential exposure to improper billings by investing in compliance programs. The American Hospital Association, for example, recently reported that 96 percent of surveyed hospitals either had a compliance program in effect or were planning to initiate one in 1999. This greater appreciation of the importance of health care fraud prevention is already paying dividends. Based upon an annual audit of Medicare fee-for-service payments, we have seen almost a 50 percent decline in improper payments during the last three years.

Second, the OIG committed to creating an atmosphere that encourages health care providers to come forward to the Government voluntarily when they uncover evidence of fraudulent conduct within their organization. In light of the substantial civil and criminal exposure faced by those charged with defrauding the Medicare program, providers understandably have been hesitant to self-disclose without guidance from the Office of Inspector General. Based on the insights gained from a pilot voluntary disclosure program, we published a detailed self-disclosure protocol in October 1998.

The protocol not only sets out recommended investigative and audit measures that a provider should undertake as part of a disclosure to the OIG, but also represents our commitment to work with the disclosing entity to resolve the problem expeditiously and fairly. I am pleased to report that over 70 health care providers have self-disclosed potentially abusive conduct to the OIG and, as a result,

millions of dollars already have been returned to the Medicare Trust Fund. The providers that have made self-disclosures have received expedited review of their disclosures, and, where appropriate, favorable treatment in the resolution of the matter. As the provider community learns more about the self-disclosure process, I am confident that good faith use of the disclosure protocol will continue to expand.

I also committed to giving health care providers a better understanding of how the OIG makes judgments regarding the use of its enforcement authorities. Through public awareness efforts, such as the publication of Special Fraud Alerts, Special Advisory Bulletins and the OIG's Work Plan, we alert the provider community of our concerns and hope to encourage self-correcting behavior. When fraud is uncovered, we look to see whether the provider took appropriate steps to prevent and detect the misconduct and whether there is a likelihood that the same or similar abuse of the Medicare program will reoccur. As part of this outreach effort, we have even taken the unprecedented step of publishing the factors that we consider in determining whether to exclude an individual or entity under our permissive exclusion authorities.

To further health care providers' understanding of the OIG's priorities and approach to addressing health care fraud, I want to briefly discuss the OIG's views on corporate integrity agreements (CIAs). Where the best interests of the programs are served by allowing the provider that has engaged in serious misconduct to continue participating in the health care programs, we generally require that the provider enter into an agreement to adopt certain integrity measures. In addition to the seven core elements of a compliance program, as set forth in the Federal Sentencing Guidelines, we require the submission of a variety of reports to the OIG and reserve the right to impose sanctions, including stipulated penalties and program exclusion, for a material breach of the agreement. CIAs almost always include provisions incorporating these seven elements, but the specific terms of a particular CIA depend on the facts and circumstances related to the case and the provider. Among the relevant factors considered in crafting a CIA are the severity and extent of the underlying misconduct, the nature and recurrence of the provider, the provider's existing compliance capabilities, and whether the case resulted from a self-disclosure.

In all cases, the OIG is prepared to consider the provider's current compliance program when we negotiate the appropriate terms of a CIA. After all, a provider is often in the best position to understand what compliance measures are most useful to its organization. Of course, we cannot always determine during settlement discussions what aspects of a provider's voluntary compliance program have proven effective and should be incorporated into the CIA. Handbooks and training materials provide us only limited information about how successfully a provider has implemented its compliance policies and procedures. The more a provider can point to tangible, positive outcomes stemming from its compliance efforts, the more reliance we can place on these measures and integrate them into a CIA.

Perhaps the best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities. As we state in the self-disclosure protocol, matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity responsible for claims processing and payment. We also recommend that the provider conduct an initial assessment to substantiate there is a problem with non-compliance with program requirements before making a disclosure to the OIG. When False Claims Act liability results from such a disclosure, the OIG can be more flexible in considering the terms of a CIA in light of the demonstrated effectiveness of the provider's compliance program. In general, we grant more deference to the existing compliance measures of a self-disclosing provider, even if those measures differ from what we might otherwise require in a CIA.

If the self-disclosing provider has demonstrated that its compliance program is effective and agrees

to maintain its compliance program as part of the False Claims Act settlement, we may not even require a CIA. That decision is influenced by a number of variables, including the scope and seriousness of the misconduct, the risk of recurrence, whether the disclosed matter was identified and reported as a result of the provider's compliance measures and the degree of the provider's cooperation during the disclosure verification process. In those cases, where in our judgment it is necessary to require the self-disclosing provider to enter into a CIA, the provider may need to make only limited changes to its existing policies and procedures to meet most of the requirements of the CIA.

For instance, in cases where the provider's own audits detected the disclosed problem, the OIG may consider alternatives to the CIA's auditing provisions. We may permit a self-disclosing provider to perform some or all of the billing audits through its internal auditors rather than require the retention of an independent review organization for each year of the CIA. In an appropriate case, we may narrow the scope and focus of the claims review to the areas found out of compliance or allow alternate audit methodologies in lieu of the statistical sampling methodology we generally require. In addition, we are more likely in a self-disclosure case to eliminate the need for an external evaluation of the provider's compliance with the terms of the CIA.

In addition to the audit provisions, many providers entering into CIAs express concern about the OIG's ability to exclude a provider if the OIG determines that the provider has materially breached the terms of the CIA. Generally, we believe that this provision is necessary to ensure that we maintain our ultimate remedy to protect Federal health care programs from problematic providers. However, a provider that has made an appropriate self-disclosure and has demonstrated sufficient trustworthiness may lead us to conclude that we can sufficiently safeguard the programs through a CIA without the exclusion remedy for a material breach. Therefore, we will forego the exclusion remedy in appropriate self-disclosure cases.

In closing, I want to thank all the health care providers and representatives of health care associations that have worked so hard with us to improve the integrity of the health care system. Through cooperative efforts and open communication, we have been able to make solid progress in the fight against health care waste, fraud and abuse. We in the OIG are committed to continuing to work with you to do an even better job in the future.

/s/

June Gibbs Brown
Inspector General