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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?



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

 Factors to consider when deciding whether to disclose

Pros

Piece of mind
Good Corporate Citizen
Single damages?
No CIA or CCA?
No exclusion

Cons

Point of no return
Other issues exposed
Referral to OIG/DOJ?
State and private entities?
Loss of control



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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



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- 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



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- 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



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- 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



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- 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



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- 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?



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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 casespecific facts



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- 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?



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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



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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



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Trend: Stark and Kickback Resolutions Limited to Overpayment



An Open Letter to Health Care Providers

April 24, 2006

Protocol (SDP). I am also amount in a minimizer that promotes the use of the SDP to resolve civil mountary penalty (CMP) liability under the physician solf-rend and anti-kickback statutes for financial arrangements between hospitals and physicians.

In addition to working with our law cultiveneum gardness to stanction companies and individual way who wholes the lows OHG Side consumination shoutheast insources to premote voluntary compliance by the inclusive, or premote voluntary compliance by the inclusive control of the control of the

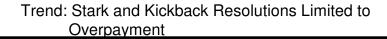
. For those providers that demonstrate the requisite level of trustworthiness and that also have in place, or are willing to develop, an effective compliance program, OIG will waive its exclusion authority concurrent with resolution of monetary liability under the False Claims Act and the CMP Law. Typically,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

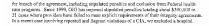
Effective compliance systems are key to strengthening the integrity of the health care system. Old integrity agreements have been a easilyst for change in corporate culture, and can result in the development of comprehensive internal control systems. Our communications with providers during the course 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 surresements. Integrity agreements twoically include contraction transitions.



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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

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 conduthat subjects the provider to CMP liability under the OIG's physician self-referral and antitikkhank atthorities—in particular situations involving a finencial benefit knowingles conferra-



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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.



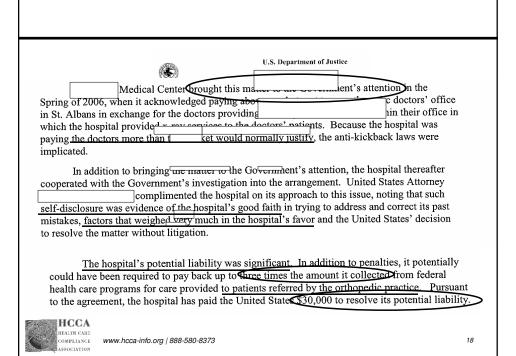
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- This is a significant benefit as compared to the huge statutory exposure of 3 times the amount received for the referred services under Stark.
- Has this open letter generated the desired disclosures?
- · Has it worked?



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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



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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 selfdisclose misconduct pursuant to a pre-existing compliance program?
- If so, there would be more incentive to come forward with potential instances of misconduct



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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.



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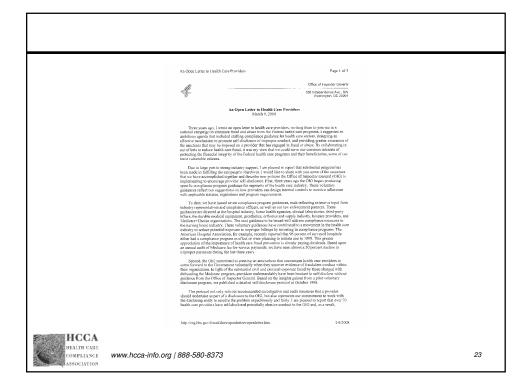
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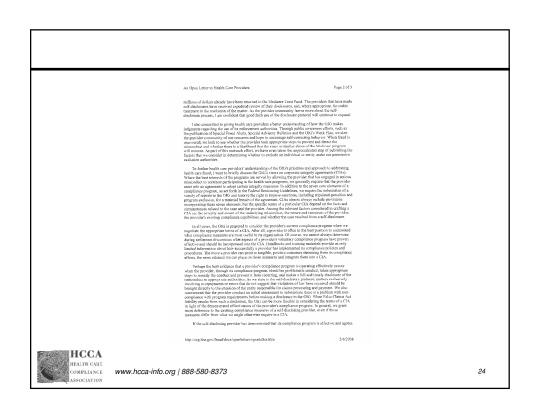
Trends in Self-Disclosure

- · Questions?
- Thank you
- John N. Joseph, Esquire Post & Schell, PC jjoseph@postschell.com



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As Open Letter to Health Case Provides

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