Recent Developments in Voluntary Disclosure Strategies

Sara Kay Wheeler, Esq., King & Spalding LLP

Overview

- OIG Self-Disclosure Protocol
- OIG Open Letters
  - March 2000
  - November 2001
  - April 2006
  - April 2008
- Complications Due to Enforcement Landscape
  - Federal Enforcement
  - Increased State Enforcement
- Practical Considerations
Self-Disclosure Protocol

Detailed text and analysis of the Self-Disclosure Protocol, including context and implications for the health care industry.
OIG Self-Disclosure Protocol

- Published in the October 30, 1998 issue of the Federal Register
  - Sets forth specific steps regarding a process by which health care organizations may work openly and cooperatively with the OIG to resolve potential fraud and abuse involving federal health care programs
  - May be used for disclosing potential violations of federal criminal, civil, or administrative laws
  - Matters exclusively involving overpayments and billing errors may be brought directly to the entity that processes claims and issues payment on behalf of the federal health care programs

OIG Self-Disclosure Protocol

- Elements
  - Basic Information
    - Identifying information
    - Detailed description of the matter being disclosed
    - Status of the internal investigation
    - Type of provider and billing numbers
    - Description of the potential violation of law and explanation of how it possibly could have occurred
    - Certification of truthfulness
OIG Self-Disclosure Protocol

• Elements
  – Substantive Information
    • Detailed description of the internal investigation according to Internal Investigative Guidelines
      – Must include a description of internal efforts to understand the issue (e.g., interviews, data analysis and document review)
      – Must include an estimate of the monetary impact of the incident or practice upon the federal health care programs
  – Self-assessment
    – Must include legal analysis addressing universe of potentially applicable federal laws
  • Findings

OIG Self-Disclosure Protocol

• The internal review may occur after an initial disclosure
• The OIG may accept or deny the provider’s request to use the Protocol
  – Providers may wish to consider how much detail to divulge prior to officially being accepted into the program
• The process should not be considered akin to a request for an advisory opinion
OIG Self-Disclosure Protocol
Use by Providers

• The Protocol in 1998
  – The OIG developed the protocol to further encourage providers to self police by adopting effective compliance programs that include processes by which potentially abusive practices may be discovered and resolved
  – However, the advantages of disclosing a potential compliance problem pursuant to the protocol were not initially evident to the health care community

OIG Self-Disclosure Protocol
Use by Providers

• Protocol Limitations in 1998
  – Unclear whether the OIG or DOJ would mount an independent investigation
  – The Protocol was relatively untested with only limited participation in the pilot program (Operation Restore Trust)
  – Protocol was designed for “billing” related issues, not “arrangements” related issues under the federal fraud and abuse laws
NO GUARANTEE!!

irregularities in their dealings with the Federal health care programs. Because a provider’s disclosure can involve anything from a simple error to outright fraud, the OIG cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will accrue to the disclosing entity. In our experience, however, opening lines of communication with, and making full disclosure to, the investigative agency at

OIG Open Letters
OIG Issues Open Letters

• Why?
  – Create confidence in the Protocol
  – Provide guidance for providers wanting to use the Protocol
  – Offer better defined incentives
  – Clarify when the protocol should be used

• When?
  – March 2000
  – November 2001
  – April 2006
  – April 2008
March 2000 Open Letter

• Issued 17 months after the Protocol was implemented

• Providers participating in the Protocol should expect:
  – expedited review
  – favorable treatment

• May not need to enter into a Corporate Integrity Agreement (CIA) if the provider can demonstrate an “effective” compliance program

March 2000 Open Letter

• Even if a CIA is required, the provider may still benefit from:
  – No requirement to engage an independent review organization (IRO)
  – No external review of the provider’s compliance program
  – Cost savings
    • reduced external auditor fees
    • reduced legal fees
    • reduced consulting fees

• BUT… apprehension about the Protocol persisted
November 2001 Open Letter

• Builds on March 2000 Open Letter
• OIG announced several significant OIG voluntary compliance initiatives:
  – announcement of compliance program guidance tailored to the operations of specific categories of health care providers
  – Special Fraud Alerts
  – Advisory Opinions

November 2001 Open Letter

• Eight factors identified as critical to OIG’s determination of whether to impose a CIA as a condition of settlement, including:
  – **Whether the provider self-disclosed**
  – The **monetary damage** to the federal health care programs
  – Whether the case involves successor liability
  – Whether the provider is currently participating in the federal health care programs or in the line of business that gave rise to the fraudulent conduct
November 2001 Open Letter

• Eight Factors Considered to Determine if a CIA is Needed (continued)
  – Whether the alleged conduct is capable of repetition
  – The age of the conduct
  – Whether the provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify such compliance to the OIG, and
  – Other circumstances as appropriate

April 2006 Open Letter

• Broadened the Protocol’s application to:
  – Civil Monetary Penalty (CMP) liability under the Physician Self-Referral Law (Stark)
  – Anti-Kickback Statute (AKS)

• Significant incentive!
  – Open Letter coincided with a substantial increase in OIG and DOJ enforcement activity surrounding hospital physician relationships
  – A new strain of CIA had emerged with mandatory procedures designed to more rigorously regulate hospital-physician contractual arrangements
April 2006 Open Letter

• Resolution of arrangements based liability
  – Confer with the DOJ to ensure that the DOJ has knowledge of such disclosures and has an opportunity to offer its opinion before the OIG accepts a provider into the protocol
  – Results of the OIG’s review are presented to the DOJ before any final resolution of the matter
  – Although any settlement reached with the OIG is not binding on the DOJ, their involvement throughout the process provides some comfort with regard to the likelihood of the DOJ’s desire to independently pursue the provider

April 2006 Open Letter

• Stark – AKS Damages Continuum
  – When issues disclosed arise due to physician arrangements it is possible that the Stark Law and AKS may be implicated
  – Under the Protocol the OIG may settle these issues at the lower end of the continuum
    • Stark - “number and dollar value of improper claims”
    • AKS - “number and dollar value of improper payments or remuneration”
April 2006 Open Letter

- The OIG “will generally settle [self-disclosed] 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”

- This distinction can be extremely significant depending on the facts and circumstances of the underlying case

April 2006 Open Letter

- Additional Incentives
  - Waive its exclusion authority if a provider demonstrated trustworthiness and the ability to develop or maintain an effective compliance program as appropriate
  - Settle self-disclosed matters under Certificate of Compliance Agreements (CCAs) (without requirements for IRO review or external audits)
April 2008 Open Letter

- Streamlines the disclosure process and articulates agency’s intent to provide timely responses to self-disclosures

- The OIG also issued further details expected in initial submissions which include the following:
  - a complete description of the conduct being disclosed
  - a description of the provider’s internal investigation (or a commitment regarding when the investigation will be completed)
  - An estimate of potential damages to the federal health care programs and the methodology used to calculate that figure (or a commitment regarding when the provider will complete such estimate)
  - A statement of the laws potentially violated by the conduct
  - **The additional details must be disclosed along with the basic information previously required under the protocol**
April 2008 Open Letter

• Once the initial disclosure is submitted, the disclosing organization is expected to complete its investigation and damages assessment within approximately three months after being accepted into the protocol

• The OIG pledges to streamline its internal review process for resolving cases

• The OIG also repeats in this letter that mere overpayments should not be disclosed through the Protocol

April 2008 Open Letter

• Evidence of an effective compliance program
  – a provider’s submission of a complete and informative disclosure
  – prompt responses to the OIG’s requests for additional information
  – the ability to conduct accurate audits

• As a result, the OIG will presume that a provider meeting the OIG’s expectations for disclosure has an effective compliance program
  – **NO CIA or CCA required as a condition of settlement**
April 2008 Open Letter

• With the presumption of an effective compliance program, the OIG seeks:
  – to further expedite the disclosure process
  – encourage more providers to disclose potential fraud under the protocol

April 2008 Open Letter

• Streamlined Process and Additional Incentives
  – Clearer requirements for the initial disclosure to the OIG
  – A more streamlined process for advancing through the Protocol
  – A presumption that if the provider meets the OIG’s expectations, the provider maintains an effective compliance program and it will not be required to enter into a CIA or CCA
Voluntary Disclosure Strategies
State-Specific Protocol

• States have begun to issue state specific audit and/or disclosure protocols to address Medicaid compliance issues. Examples include
  – Texas, Georgia, New York and Montana

• As providers and Medicaid managed care plans assess potential Medicaid overpayments a/o fraud and abuse, an understanding of any potentially available state-specific protocol is critical

Voluntary Disclosure Strategies
State-Specific Protocol

• Texas Provider Self-Reporting Guidance
  (https://oig.hhsc.state.tx.us/ProviderSelfReporting/Self_Reporting.aspx)
  – Purposefully general and flexible
  – The TX OIG expects that if a provider uncovers an “ongoing violation” the provider will immediately contact the OIG prior to continuing any internal review or investigation
  – A written notification must be sent on the required form
Voluntary Disclosure Strategies
State-Specific Protocol

- Texas Managed Care Organization: Special Investigative Units or Contracts (TX Govt. Code Sec. 531.113(b)(2))
  - Each managed care organization in TX must establish and maintain a special investigative unit or contract with an entity to investigate fraudulent claims and other types of program abuse by recipients and service providers
  - Mandatory reporting of possible acts of fraud or abuse to the commission's office of inspector general

Voluntary Disclosure Strategies
State-Specific Protocol

- Georgia (Ga. DCH Policy and Procedure Manual (Part 1), § 304.10)
  - Manual outlines the “methodology used… in determining the amount of the overpayment”
  - Letter should be accompanied by a Corrective Action Plan (CAP)
  - DCH must approve the disclosure and CP
  - Appeal rights may be implicated
Voluntary Disclosure Strategies
State-Specific Protocol

- Montana Medicaid Provider Self-Disclosure/Self-Audit Policy and Procedure
  - Effective August 25, 2006,
  - Offers several audit options for providers including use of the HHS OIG Voluntary Disclosure Protocol
  - The Protocol provides preferred audit methods and encourages self-disclosure
  - Applicable to fee-for service and managed care providers (disclosure must be made directly to the Medicaid agency)
  - Currently under revision

Voluntary Disclosure Strategies
State-Specific Protocol

- New York Medicaid Inspector General Voluntary Disclosure Program
  - Draft issued in July of 2008
  - Program currently under revision and not in use or available for public review
  - Self disclosures may be made in the interim by directly contacting the Medicaid Office of Inspector General
  - Revised Program draft currently under review for approval and release
Voluntary Disclosure Strategies
State-Specific Protocol

- New York Mandatory Compliance Proposed Rule
  - Issued January 14, 2009; comments due in 45 days
  - Providers receiving more than $500,000 in Medicaid dollars must implement compliance programs including:
    - Written policies and procedures
    - Employee responsible for day to day compliance activity
    - Education and training
    - Lines of communication to report potential compliance issues
    - Disciplinary policies to encourage good faith participation in the compliance program
    - System to identify compliance issues
    - System to respond to compliance issues
    - Policy of non-intimidation and non-retaliation

Practical Tips

- Each Open Letter provides clarification and greater incentives, however a provider should carefully consider options
  - Is this an issue that can be resolved with a disclosure?
  - Should the provider disclose and if so, to whom?
    - Who within the organization should be involved in this decision?
    - What is the role of the compliance department and compliance officer? Under what regulatory framework would disclosure be most beneficial?
    - Who needs to be briefed and at what stage in the process?
Practical Tips

• Providers participating in multiple federal health care programs should be aware of the various disclosure methods available
  – Carrier, intermediary
  – OIG
  – State Agency
  – DOJ
  – CMS

• Determine whether the issue implicates one or more of the regulatory constructs

Practical Tips

• Consult experienced counsel. This may be in-house or outside counsel
  – Document steps pursued

• Be familiar with the jurisdiction of the agencies that may potentially receive the disclosure
  – What type or release do you need?
  – Are the agencies involved that can provide the needed release?

• Be as prepared as possible prior to contacting the agency
  – Understand the underlying conduct and potential financial exposure
Practical Tips

• Explore all of your organization’s options for disclosure

• Pursue appropriate steps to determine the best option for your organization based on the facts and circumstances at issue

• Be familiar with the applicable law (see chart on the next slide)

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<td>Stark Civil Monetary Penalty</td>
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Speaker’s Contact Information

Sara Kay Wheeler  
King & Spalding LLP  
(404) 572-4685  
skwheeler@kslaw.com