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October 21, 2010

OIG Shares Key Insights On When Owners, Officers & Managers Face OIG Program Exclusion Based On Health Care Entity Misconduct

The Department of Health & Human Services Office of Inspector General (OIG) this morning posted to its website key guidance about when OIG will exercise its authority under the permissive exclusion rules of Social Security Act (Act) § 1128(b)(15)(A)(ii) to exclude from Federal health program participation owners, officers or managing employees of health care organizations based on their role, involvement or ownership interest in a health industry company convicted of certain offenses or excluded from Federal health program participation.

The **Guidance For Implementing Permissive Exclusion of Authority under Section 1128(b)(15) of the Social Security Act** (Guidance) provides valuable insights for health care organizations, their owners, officers and managers about how OIG expects them to act and the evidence that OIG likely will require should OIG bring an OIG exclusion action against them personally following the conviction or OIG exclusion of their health care organization for misconduct. To position themselves to survive OIG or related exclusion or prosecution, health care organizations and their owners, officers and management use the Guidance as a guide to help strengthen the defensibility of their daily actions against potential OIG scrutiny and consider the advisability of updating their personal and organizational practices, policies and leadership training in response to this Guidance.

OIG Authority To Exclude Officers, Managers & Owners of Excluded, Convicted Health Care Entities

Section 1129(b)(15)(A)(ii) gives OIG discretionary authority to exclude an individual owner, officer, or managing employee of an, entity convicted of certain offenses or excluded from participation in the Federal health care programs. Derivative in nature, Act § 1128(b)(15) exclusions are based upon the individual's role or interest in a company that is excluded or is convicted of certain offenses. OIG's exercise of this discretion is not subject to administrative or judicial review.

Act § 1128(b)(15) provides two different bases for exclusion:

- "Officers" and "managing employees" within the meaning of Act § 1126(b) may be excluded under Act § 1128(b)(15)(A)(ii) based solely on their position within the entity; and
- Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under Act § 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the sanction.

The Guidance discusses the guiding principles and core factors and presumptions that OIG generally will apply to decide if the OIG will should exclude an individual from Federal health program participation based on the involvement of the individual as an owner, officer or manager of company that has been excluded from Federal program participation or convicted of certain health care crimes.. Consequently, owners, officers and managers alike concerned about their exposure to Federal program exclusion or other personal liability under Federal health care fraud laws should use the Guidance to help strengthen their ability to avoid personal exclusion or other prosecution by the OIG as a result of their involvement with a health care organization excluded from Federal program participation or convicted of other crimes.

Exclusion Guidelines For Officer, Management Employee vs. Owner

Unlike the requirement for exclusion of an owner, the Act does not condition the OIG's authority to exclude an officer or management employee on evidence that the individual knew or should have known of the organization's misconduct. According to the Guidance, however, the OIG does not intend to use this distinction in its statutory authority to exclude all officers and managing employees. Rather, the Guidance reflects that the OIG generally will require some evidence of knowledge or deemed knowledge as a prerequisite to exercise of its exclusionary authority

against an officer or management employee. In this respect, the Guidance states that a presumption in favor of exclusion will apply if OIG finds evidence that an officer or a managing employee knew or should have known of the conduct. As with the presumption relating to owners, the presumption may be overcome when OIG finds that significant factors weigh against exclusion.

For an owner, the Act and Guidance require evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. If the evidence supports a finding that an owner knew or should have known of the conduct, the OIG will presume that the owner should be excluded unless the OIG finds that significant factors weigh against exclusion.

Factors For Making Knowledge Determinations

According to the Guidance, when considering whether to exclude an individual under section 1128(b)(15), the OIG will consider the knowledge, involvement and participation of the individual in the organizations misconduct. For this purpose, OIG generally will consider the basis for the criminal conviction and/or exclusion of the entity, as well as any other conduct that formed the basis for criminal, civil, or administrative investigations, cases, charges, or resolutions. In addition, OIG will consider matters that involve entities that are or were related to the convicted or excluded entity. For example, OIG will consider the conduct alleged by the Government in a civil False Claims Act settlement with a corporate parent of the convicted or excluded entity.

According to the Guidance, the factors that the OIG will consider in making these determinations generally will include:

- Circumstances of the Misconduct and Seriousness of the Offense including:
  - ✓ What were the nature and scope of the misconduct for which the entity was sanctioned? What were the nature and scope of any other relevant misconduct? At what level of the entity did the misconduct occur (e.g., violation by one field employee of company policy versus headquarters' involvement and/or direction)?
  - ✓ What was the criminal sanction imposed against the entity (or related entities) or any individuals? What was the amount of any criminal fine, forfeiture, or penalty imposed? What was the amount of any civil or administrative payment regarding related or similar issues? What was the length of any period of exclusion imposed?
  - ✓ Was there evidence that the misconduct resulted in (1) actual or potential harm to beneficiaries or other individuals or (2) financial harm to any Federal health care program or any other entity? If financial loss to the programs or other persons occurred, what was the extent?
  - ✓ Was the misconduct an isolated incident or part of a pattern of wrongdoing over a significant period of time? Has the entity previously had similar problems with OIG, the Centers for Medicare & Medicaid Services or its contractors, or any other Federal or State regulatory agency? What was the nature of these problems?
- Individual's Role in Sanctioned Entity
  - ✓ What is the individual's current position and what positions has the individual held with the entity throughout his or her tenure, particularly at the time of the underlying misconduct? What degree of managerial control or authority is involved in the individual's position?
  - ✓ What was the relation of the individual's position to the underlying misconduct? Did the misconduct occur within the individual's chain of command?
- Individual's Actions in Response to the Misconduct
  - ✓ Did the individual take steps to stop the underlying misconduct or mitigate the ill effects of the misconduct (e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for the sanction or other corrective action)? Did these actions take place before or after the individual had reason to know of an investigation? If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.
  - ✓ Did the individual disclose the misconduct to the appropriate Federal or State authorities? Did the individual cooperate with investigators and prosecutors and respond in a timely manner to lawful requests for documents and evidence regarding the involvement of other individuals in a particular scheme?
- Information About the Entity
  - ✓ Has the sanctioned entity or a related entity previously been convicted of a crime or found liable, civilly or administratively, or resolved a civil or administrative case with the Federal or State Government or a government entity? If so, what was the prior conduct that formed the basis for these actions?
  - ✓ What is the size of the entity (e.g., how many employees does the entity have, what are the revenues, how many product lines/divisions are there within the entity)? What is the corporate structure of the entity (e.g.,

how many subsidiaries (operating and nonoperating) are there, what are the sizes of the subsidiaries, and what are the reporting relationships between the subsidiaries)?

Using Guidelines To Manage Organizational & Personal Exposure To OIG Exclusion

Because these OIG has identified these factors as core considerations in its exclusion analysis, the Guidance provides invaluable guidance for health care entities, their owners, officers and management employees about opportunities position their conduct for defensibility against OIG enforcement exposures.

To properly understand and use this Guidance, however, health industry leaders must keep in mind their limitations.

First, OIG views the factors listed in the Guidance as "internal agency guidelines" subject to modification at any time. Second the list of factors in the Guidance is not exclusive. OIG does not consider the Guidance or the listing of factors as a limitation on its discretionary authority to exclude individuals or entities that pose a risk to Medicare and other Federal health care programs or program beneficiaries, or to create any rights or privileges in favor of any party or as supplanting or modifying any OIG regulations under 42 CFR part 1001, governing program exclusions. Consequently, health care organizations and their leaders and owners must continue to make overall compliance a priority and to strive to monitor and comply with the constantly evolving standards and requirements of the OIG and other federal and state programs.

Despite these limitations, the Guidance provides invaluable guidance for health care owners, officers and management employees about how they should conduct themselves and the evidence they should seek to create and preserve concerning their ongoing commitment to compliance, management compliance efforts, and investigation and response to potential or suspected misconduct within their organization. Clearly, each health care leader, owner and health are organization should incorporate this knowledge into his personal operating intelligence and encourage the health care organizations with whom they are involved to review and strengthen their practices, policies, operations, and leadership and compliance training to leverage the insights contained in the Guidance.

For More Information or Assistance

If you need assistance evaluating or responding to this development of other health care compliance, risk management, transactional, operational, reimbursement, enforcement or public policy concerns, please contact the author of this update, Cynthia Marcotte Stamer, at (469) 767-8872, **cstamer@Solutionslawyer.net**.

Vice President of the North Texas Health Care Compliance Professionals Association, Past Chair of the ABA Health Law Section Managed Care & Insurance Section and the former Board Compliance Chair of the National Kidney Foundation of North Texas, Ms. Stamer has more than 23 years experience advising health industry clients about these and other matters. A popular lecturer and widely published author on health industry concerns, Ms. Stamer continuously advises health industry clients about compliance and internal controls, workforce and medical staff performance, quality, governance, reimbursement, and other risk management and operational matters. Ms. Stamer also publishes and speaks extensively on health and managed care industry regulatory, staffing and human resources, compensation and benefits, technology, public policy, reimbursement and other operations and risk management concerns. Her insights on these and other related matters appear in the Health Care Compliance Association, Atlantic Information Service, Bureau of National Affairs, World At Work, The Wall Street Journal, Business Insurance, the Dallas Morning News, Modern Health Care, Managed Healthcare, Health Leaders, and a many other national and local publications. For additional information about Ms. Stamer, her experience, involvements, programs or publications, see **here**.

Other Recent Developments

If you found this information of interest, you also may be interested in reviewing some of the following recent Updates available online by clicking on the article title:

- **CMS Delegated Lead Responsibility For Development of New Affordable Care Act-Required Medicare Self-Referral Disclosure Protocol**
- **HHS announces Rules Implementing Tools Added By Affordable Care Act to Prevent Federal Health Program Fraud**
- **HHS announces Rules Implementing Tools Added By Affordable Care Act to Prevent Federal Health Program Fraud**
- **Monday 9/13 Deadline To Comment Proposed HITECH Act HIPAA Privacy Rules; 9/14 Meeting Studies Proposed Changes**
- **OIG: Texas Overbilled Medicaid for Medical Transportation Costs**

- **DMEPOS Suppliers Face 9/27 Deadline To Meet Tightened Medicare Standards**
- **Initial EHR Certification Bodies Named**
- **HHS Announces Adjustments to Federal Medical Assistance Percentage (FMAP) Rates**
- **CMS Publishes Corrections To Proposed 2011 Physician Fee Schedule Rules**
- **Medicare Changing How It Pays For Outpatient Dialysis**
- **Last Call: Today Deadline To Comment on Proposed Edits To CMS Nursing Home Civil Monetary Penalty Regs**
- **Rite Aid Agrees to Pay $1 Million to Settle HIPAA Privacy Case As OCR Moves To Tighten Privacy Rules**
- **HHS Invites Input On Medicaid Changes To Promote Children's Health Quality**
- **CMS Adopts ESRD Facility Prospective Payment System & Proposes New Quality Incentive Program**
- **CMS Rule Clarifies When Outpatient Services Subject to 3-Day Rule & Finalizes FY 2011 Inpatient Payment Rates**
- **New Affordable Care Act Mandated High Risk Pre-Existing Condition Insurance Pool Program Regulations Set Program Rules, Prohibit Plan Dumping of High Risk Members**
- **CMS & ONC To Co-Host 7/22 ONC Certification & Medicare/Medicaid EHR Incentive Program Audio Training**
- **CMS Proposes Changes To Civil Monetary Penalty Rules For Nursing Homes**

For More Information

We hope that this information is useful to you. You can review other recent health care and internal controls resources and additional information about the health industry and other experience of Ms. Stamer **here**. If you or someone else you know would like to receive future updates about developments on these and other concerns, please be sure that we have your current contact information – including your preferred e-mail – by creating or updating your profile at **here** or e-mailing this information **here**. To unsubscribe, e-mail **here**.