

Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act

SUMMARY: This notice sets forth nonbinding factors the Office of Inspector General (OIG) will consider in deciding whether to impose permissive exclusion in accordance with section 1128(b)(15)(A)(ii) of the Social Security Act (the Act), which authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.

SUPPLEMENTARY INFORMATION

I. Purpose and Rationale

Section 1128(b)(15) of the Act authorizes the Secretary, and by delegation the Inspector General, to exclude an individual owner, officer, or managing employee of a sanctioned entity, as defined in section 1128(b)(15)(B) (*i.e.*, an entity that has been convicted of certain offenses or excluded from participation in the Federal health care programs). Exclusions under section 1128(b)(15) of the Act are derivative in nature and are based upon the individual's role or interest in a company that is excluded or is convicted of certain offenses. Exclusions under section 1128(b)(15) are permissive, that is, the Secretary has the discretion whether to exclude or not to exclude. OIG's exercise of this discretion is not subject to administrative or judicial review.

Section 1128(b)(15) of the Act provides two different bases for exclusion. Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under section 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the sanction. Officers and managing employees, as defined in section 1126(b) of the Act, may be excluded under section 1128(b)(15)(A)(ii) based solely on their position within the entity.

Because the elements of these two provisions are so different, our exclusion analysis differs depending on whether the individual in question is: (1) an owner or (2) an officer or a managing employee.

The statute sets a higher standard for exclusion of an owner, requiring evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome when OIG finds that significant factors weigh against exclusion.

With respect to officers and managing employees, the statute includes no knowledge element. Therefore, OIG has the authority to exclude every officer and managing employee of a sanctioned entity. A “managing employee” is defined as an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity. While OIG does not intend to exclude all officers and managing employees, when there is evidence that an officer or a managing employee knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. As with the presumption relating to owners, the presumption may be overcome when OIG finds that significant factors weigh against exclusion.

OIG will consider the factors set forth below in deciding whether to exclude an officer or a managing employee in the absence of evidence that the person knew or should have known of the misconduct. We believe that these factors will serve a number of useful purposes: (1) they will allow for the development of effective investigations and investigative plans by OIG and its law enforcement partners, (2) they will establish and publicize a framework that will serve as a basis for OIG’s permissive exclusion decisions, (3) they will allow for the appropriate allocation of OIG’s finite resources to actions that have the most remedial and deterrent effect, and (4) they will positively influence individuals’ future behavior and compliance with Federal health care program requirements by holding individuals accountable for misconduct within entities in which they are in positions of responsibility.

These factors are internal agency guidelines that may be subject to modification at any time. They are not intended to limit OIG’s discretionary authority to exclude individuals or entities that pose a risk to Medicare and other Federal health care programs or program beneficiaries, nor do they create any rights or privileges in favor of any party. Further, these factors do not supplant or modify, in any way, the OIG regulations, codified at 42 CFR part 1001, governing program exclusions.

These factors were derived from multiple sources, including: (1) the regulations governing exclusions under sections 1128(b)(15) and 1128A of the Act (42 CFR parts 1001 and 1003); (2) the factors for implementation of permissive exclusion under section 1128(b)(7) (62 Fed. Reg. 67392 (Dec. 17, 1997)); (3) the responsible corporate official doctrine established in case law, including *U.S. v. Park*, 421 U.S. 658 (1975); and (4) decisions of the Departmental Appeals Board in exclusion matters.

II. Factors To Be Considered in Implementing OIG’s Permissive Exclusion Authority Under Section 1128(b)(15)(A)(ii)

OIG may use the following factors to determine whether to impose a permissive exclusion under section 1128(b)(15)(A)(ii) of the Act in a particular case. They are

informal and nonbinding. The presence or absence of any or all of these factors does not constitute the sole grounds for determining whether OIG will pursue exclusion.

When considering whether to exclude an individual under section 1128(b)(15), OIG 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. As used in the following factors, the term “misconduct” includes the factual basis for the criminal conviction or exclusion that underlies the potential 1128(b)(15) exclusion as well as any other conduct OIG considers relevant, including allegations in criminal, civil, and administrative matters involving the convicted or excluded entity or any related entity.

A. Circumstances of the Misconduct and Seriousness of the Offense

1. 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)?
2. 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?
3. 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?
4. 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?

B. Individual’s Role in Sanctioned Entity

1. What is the individual’s current position? 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?

2. What was the relation of the individual's position to the underlying misconduct? Did the misconduct occur within the individual's chain of command?

C. Individual's Actions in Response to the Misconduct

1. 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.
2. 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?

D. Information About the Entity

1. 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?
2. 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)?