Criteria for implementing section 1128(b)(7) exclusion authority
April 18, 2016

Preamble

Under section 1128(b)(7) of the Social Security Act (the Act), the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services may exclude any individual or entity (collectively, "person") from participation in the Federal health care programs for engaging in conduct prohibited by sections 1128A or 1128B of the Act. In 1997, OIG published a policy statement with non-binding criteria to be used by OIG in assessing whether to impose exclusion under section 1128(b)(7). See 62 Fed. Reg. 67,392 (December 24, 1997). Since the original publication of the policy statement, OIG has used these criteria to evaluate whether to impose exclusion under section 1128(b)(7); release this authority in exchange for integrity obligations with OIG, within this document we refer to both "integrity obligations" or corporate integrity agreements (CIA) interchangeably; or take some other approach. OIG solicited information and recommendations for revising these criteria on June 27, 2014. OIG received five comments from the public. Based on its experience in evaluating persons for exclusion and on the comments received in response to the solicitation, OIG has revised the non-binding criteria for use in evaluating exclusion under section 1128(b)(7).

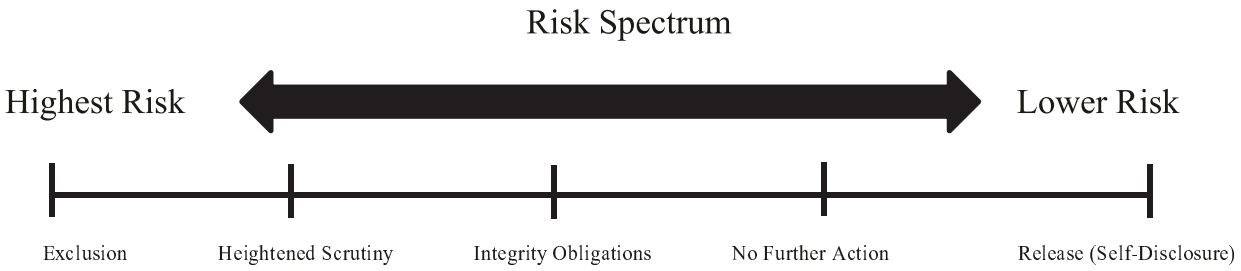
This revised policy statement supersedes and replaces the 1997 Federal Register notice.

Background

Exclusion is a remedial measure designed to protect the Federal health care programs from any person whose continued participation in the programs constitutes a risk to the programs and their beneficiaries. Federal health care programs may not pay for any items or services furnished, ordered, or prescribed by an excluded person. OIG has discretion as to whether to impose exclusion under section 1128(b)(7).

The question of whether to exercise exclusion authority under section 1128(b)(7) often arises in the context of False Claims Act matters. Health care fraud that subjects a person to liability under the False Claims Act, 31 U.S.C. §§ 3729 – 3733, will generally also subject that person to liability under section 1128(b)(7). In determining whether to exercise its discretion under section 1128(b)(7), OIG presumes that some period of exclusion should be imposed against a person who has defrauded Medicare or any other Federal health care program. This presumption in favor of exclusion is rebuttable in certain situations. This document sets forth circumstances in which the presumption may be rebutted and the non-binding factors that OIG will use to make such a determination. This document also describes how OIG evaluates risk to the Federal health care programs in using its other available remedies.

OIG evaluates health care fraud cases on a continuum: resolution of OIG's exclusion authorities is based on OIG's assessment of future risk to the Federal health care programs.



OIG often concludes that exclusion is not necessary to protect the Federal health care programs if the person agrees to appropriate integrity obligations. In these cases, OIG will require integrity obligations in exchange for a release of OIG's 1128(b)(7) exclusion authority. The goals of CIAs are to strengthen a person's compliance program and promote compliance so that future issues can be prevented or identified, reported, and corrected. Integrity obligations also enhance OIG's oversight of the person.

In relatively rare circumstances, OIG has determined that a CIA is necessary but the person has refused to agree to appropriate integrity obligations with OIG. In these situations, OIG evaluates whether to pursue exclusion or whether other administrative actions, such as use of its authorities under the Inspector General Act, are appropriate to monitor the person's compliance with Federal health care programs (known as "unilateral monitoring"). For example, in addition to making referrals to the Centers for Medicare and Medicaid Services (CMS) contractors for claims reviews, OIG has audited, evaluated, and investigated persons after fraud settlements where integrity provisions are not in place to protect the Federal health care programs.

Integrity obligations do not guarantee that fraud will not occur in the future. However, OIG believes that integrity obligations with OIG oversight mitigate that risk. Persons under CIAs demonstrate responsibility for their past conduct by accepting OIG oversight. OIG considers persons that have refused to enter into CIAs a greater continuing compliance risk to the programs than persons that have entered into CIAs. OIG will continue to use various tools, including unilateral monitoring and providing information to the public, to mitigate these compliance risks.

OIG also sometimes concludes that a person presents a relatively low risk to Federal health care programs so that neither exclusion nor integrity obligations are necessary. OIG typically determines that relatively low risk exists in two situations. First, in the absence of egregious conduct such as patient harm or intentional fraud, relatively low financial harm weighs in favor of not requiring integrity obligations. In making this

determination, OIG considers the financial loss to the Federal health care programs in proportion to the size of the entity, e.g., whether the person is an individual or small entity (one with 50 or fewer employees or independent contractors) or a larger entity. Second, there may be less risk when the person with whom the Government is resolving a fraud case is a successor owner. In determining whether to require integrity obligations with a successor, OIG will consider whether the new owner: (1) purchased the entity after the fraudulent conduct occurred; (2) has an existing compliance program; (3) does not have a prior history of wrongdoing or fraud settlements with the United States; (4) took appropriate steps to address the predecessor's misconduct and reduce the risk of future misconduct; and (5) can demonstrate other facts and circumstances as relevant to each unique situation.

OIG reserves its exclusion authorities in a False Claims Act settlement agreement for one of several reasons: OIG is closing its case against the person, OIG is considering unilateral monitoring, or OIG is considering exclusion. Reservation does not necessarily mean that OIG has concluded the person poses a low risk to the Federal health care programs. Prior to settlement, a person can ask, and OIG will explain, whether a reservation of its exclusion authorities indicates that OIG has determined that the person is higher risk or lower risk.

There are two limited circumstances in which OIG will usually give a person a release of 1128(b)(7) exclusion without requiring integrity obligations: (1) when the person self-discloses the fraudulent conduct, cooperatively and in good faith, to OIG; or (2) when the person agrees to robust integrity obligations with a State or the Department of Justice and OIG determines these obligations are sufficient to protect the Federal health care programs.

In summary, OIG has a range of administrative options it can exercise. Depending on the facts and circumstances presented, OIG will usually pursue one of the following approaches with respect to a person when settling a civil or administrative health care fraud case: (1) exclusion; (2) heightened scrutiny (e.g., implement unilateral monitoring); (3) integrity obligations; (4) take no further action; or (5) in the case of a good faith and cooperative self-disclosure, release 1128(b)(7) exclusion with no integrity obligations.

Applying Factors to Decide Whether to Exclude

OIG will weigh various factors described below in its determination of where a person falls on the compliance risk spectrum. At the Highest Risk end of the spectrum, OIG will pursue exclusion. At the Lower Risk end of the spectrum (cooperative and good faith self-disclosures), OIG will provide an exclusion release without integrity obligations. In

evaluating a person's place on the risk spectrum, OIG considers the facts relevant to each factor to determine how to weigh that factor.[1]

The following factors are listed under four broad categories: nature and circumstances of conduct, conduct during the Government's investigation, significant ameliorative efforts, and history of compliance. Each factor: (1) indicates a higher risk; (2) indicates a lower risk; or (3) is neutral to the risk assessment.

Nature and Circumstances of Conduct

- *Adverse Impact on Individuals*
    - Conduct that causes or had the potential to cause any adverse physical, mental, financial, or other impact to program beneficiaries, recipients, or other patients indicates higher risk.
    - A lack of patient harm does not affect the risk assessment.
- *Financial Loss*
    - The greater the amount of actual or intended loss to Federal health care programs, the higher the risk.
- Conduct that occurs as part of a pattern of wrongdoing indicates higher risk.
- Conduct that occurs over a substantial period of time indicates higher risk.
- Conduct that is continual or repeated indicates higher risk.
- Conduct that is currently ongoing or conduct that the person continued to engage in until or after the person learned of the Government's investigation indicates higher risk.
- The absence of criminal sanctions does not affect the risk assessment.

[1] In deciding whether to exclude a person or pursue alternative remedies, OIG also considers whether the person is a sole source of essential specialized items or services in a community or provides items or services for which there are no alternative or comparable sources. While these facts do not necessarily indicate that a person presents a higher or lower risk to Federal health care programs, their presence will weigh in favor of OIG pursuing remedies other than exclusion.

- *Leadership Role*

    - In the case of an individual, if the individual organized, led, or planned the unlawful conduct, this indicates higher risk.

    - In the case of an entity, if individuals with managerial or operational control at or on behalf of the entity organized, led, or planned the unlawful activity, this indicates higher risk.

- *History of Prior Fraudulent Conduct*

    - A person's history of judgments, convictions (as defined at section 1128(i) of the Act), decisions, or settlements in prior federal or state criminal, civil, or administrative enforcement actions indicates higher risk.

    - If the person previously refused to enter into a CIA, this indicates higher risk.

    - If the person is or was previously under a CIA, this indicates higher risk.

    - If the person was previously under a CIA and breached the CIA, or lied or failed to cooperate with OIG while under a CIA, this indicates higher risk.

<u>Conduct During Investigation</u>

- If the person obstructed or impeded, or attempted to obstruct or impede, the investigation, audit, or internal or external reporting of the unlawful conduct, this indicates higher risk.

- If the person took any steps to conceal the conduct from the Government or others, this indicates higher risk.

- The inability of a person to engage in the conduct again because a contract or arrangement was terminated, or due to a change in the Federal health care program rules, does not affect the risk assessment.

- Prompt response to a subpoena is expected and does not affect the risk assessment.

- Failure to comply with a subpoena within a reasonable period of time indicates higher risk.

- *Internal Investigation*

    - If the person initiated an internal investigation before becoming aware of the Government's investigation to determine who was responsible for the conduct, and shared the results of the internal investigation with the government, this indicates lower risk.

    - If the person self-disclosed the conduct cooperatively and in good faith as a result of the internal investigation, prior to becoming aware of the Government's investigation, this indicates lower risk.

- If the person clearly demonstrates acceptance of responsibility for the conduct, this indicates lower risk.

- *Cooperation*

    - If the person cooperated with or agrees to cooperate with the Government, this indicates lower risk.

    - If the person's cooperation resulted in a criminal, civil, or administrative action or resolution with or against other individuals or entities, this further indicates lower risk.

- *Resolution*

    - An adverse licensure action as a result of the conduct indicates higher risk.

    - A criminal resolution indicates higher risk. For purposes of this factor, a criminal resolution includes (1) a "conviction" as defined at section 1128(i); (2) a Deferred Prosecution Agreement; or (3) a Non-Prosecution Agreement. The nature of the criminal resolution bears on the degree of higher risk.

    - The inability to pay an appropriate monetary amount (including damages, assessments, and penalties) to resolve a fraud case indicates higher risk.

<u>Significant Ameliorative Efforts</u>

- *Significant changes in the entity.*

    - If the entity has taken appropriate disciplinary action against individuals responsible for the conduct, this indicates lower risk.

- If the entity has devoted significantly more resources to the compliance function, this indicates lower risk.

- If, since the end of the conduct at issue, the entity has been sold in an arm's-length transaction to a non-affiliated, independent third party with a history of compliant participation in the Federal health care programs, this indicates lower risk.

- If a licensed individual has obtained relevant additional training, retained a proctor or a mentor, or took similar steps to improve his or her ability to practice as a provider of health care items or services to the Federal health care programs, this indicates lower risk.

History of Compliance

- If the person has a history, prior to becoming aware of the investigation, of significant self-disclosures made appropriately and in good faith to OIG, CMS (for Stark law disclosures), or CMS contractors (for non-fraud overpayments), this indicates lower risk.

- The existence of a compliance program that incorporates the U.S. Sentencing Commission Guidelines Manual's seven elements of an effective compliance program does not affect the risk assessment.

- The absence of a compliance program that incorporates the U.S. Sentencing Commission Guidelines Manual's seven elements of an effective compliance program indicates higher risk.