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Legal Lines

OIG Issues New Guidance on Permissive Exclusion

Stuart J. Vogelsmeier, J.D., Lashly & Baer, P.C.

On April 18, 2016, the Office of Inspector General (“OIG”) issued new guidance on “permissive exclusion” (the “Guidance”). 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. The OIG has discretion as to whether to impose exclusion under section 1128(b)(7). In determining whether to exclude a person, the 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 under certain circumstances. The Guidance indicates that the OIG will weigh various factors in its determination of where a person falls on the compliance risk spectrum. At the “High Risk” end of the spectrum, exclusion is pursued. At the “Low Risk” end of the spectrum, the OIG will provide an exclusion release without corporate integrity agreements. In evaluating a person’s place on the risk spectrum, the OIG considers the facts relevant to the following four factors:

Nature and Circumstances of Conduct:

- Conduct that causes or has the potential to cause adverse physical, mental, financial, or other impact to program patients would indicate a higher risk, but a lack of patient harm does not affect the risk assessment.
- The greater that actual or intended loss to Federal health care programs, the higher the risk.
- Conduct that occurs as part of a pattern of wrongdoing, occurs over a substantial period of time, or is repeated, indicates higher risk.
- Prior fraudulent conduct indicates a higher risk, but the absence of criminal sanctions does not affect the risk assessment.
- If leadership of an entity led or planned the unlawful activity, the risk is higher.

Conduct During the Investigation:

- Lack of cooperation indicates a higher risk.
- Initiation of an internal investigation before becoming aware of the government’s investigation indicates lower risk.
- Prompt response to a subpoena is expected and does not affect the risk assessment, but failure to comply with a subpoena indicates higher risk.
- Self-disclosure indicates lower risk.
- Cooperation with the government indicates lower risk.
- An adverse licensure action as a result of the conduct indicates higher risk.

Significant Ameliorative Efforts:

- Disciplinary action against responsible individual(s) indicates lower risk.
- Devoting significant resources to the compliance function indicates lower risk.
- Sale of the entity to a non-affiliated person with a history of compliance indicates lower risk.
- Obtaining additional training indicates lower risk.

History of Compliance:

- History of self-disclosures indicates lower risk.
- Although the existence of a compliance program will not affect the risk assessment, absence of a compliance program indicates higher risk.

While the criteria identified in the Guidance by the OIG are non-binding in individual circumstances, the Guidance gives providers with insight into the OIG’s views on exclusion.

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Stuart Vogelsmeier is a partner with the St. Louis law firm of Lashly & Baer, P.C. Mr. Vogelsmeier regularly counsels health care providers on issues such as Stark Law and Anti-Kickback Law compliance, corporate structure, employment agreements, joint ventures, adding ancillary services to practices, and compliance programs. He can be contacted at (314) 436-8349 or at sjvogels@lashlybaer.com. The firm’s website is www.lashlybaer.com.

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