OIG Issues Revised Exclusion Guidance That Emphasizes The Need For An Effective Compliance Program

4.22.2016

In what has become an annual event, during his remarks to over 3,000 healthcare compliance professionals at the HCCA Compliance Institute, on April 18, 2016, Department of Health and Human Services Inspector General Daniel Levinson announced a major regulatory development. This year, Mr. Levinson announced the issuance of revised Guidance for the imposition of permissive exclusions under the OIG's exclusion authority. The new Guidance, which appears on the OIG's website and replaces the 1997 version, provides new insight on what the government will look at when deciding to impose an exclusion under section (b)(7) related to civil and administrative healthcare fraud settlements. Under section (b)(7), the OIG presumes that exclusion is appropriate for some period of time for those that have defrauded Medicare or any other Federal healthcare program. The Guidance is designed to identify those circumstances that pose a lower risk to the Federal healthcare programs to rebut this presumption for exclusion, as well as those higher risk areas that support heightened sanctions, including exclusion.

The Guidance sets forth four broad categories of factors that will be considered in assessing the risk and corresponding sanctions, which include: (1) the nature and circumstances of the conduct, (2) the cooperation and conduct during the Government's investigation, (3) significant ameliorative efforts, and (4) the provider's history of compliance. Within each category, the OIG sets forth the risk associated with certain conduct falling within each factor and ranks them relative to the associated risk on a spectrum ranging between "higher risk," "lower risk" or "neutral" (no risk) for purposes of the assessment.

Those factors that suggest a higher risk for future fraud include a history of prior fraudulent activity, a prior Corporate Integrity Agreement or a leadership role in the unlawful conduct. The

Related Services

Health Care

Health Care Industry Team

sanction is either exclusion or heightened scrutiny.

Where the OIG's assessment of the factors places the person on the lower end of the risk spectrum, the likely result is an exclusion release, with little to no further integrity obligations. Under the Guidance, lower risk factors are those actions that show overall cooperation with the government and robust corrective actions, such as self-disclosure, disciplinary actions against responsible individuals and robust compliance programs.

The overarching tenor of the Guidance is clear: having an effective compliance program—one that is an integral part of a provider's daily operations—is not optional. While having a compliance program that incorporates the seven elements of an effective program identified in the U.S. Sentencing Guidelines alone does not affect the risk assessment, not having one "indicates higher risk." As Inspector General Levinson stated, and the Guidance makes clear, self-disclosure, whether to the OIG, CMS (Stark only) or a CMS contractor (voluntary repayment) is evidence of an effective compliance program.

While the Guidance is non-binding, it is another tool that providers should at least consider when tailoring their activities generally, and more specifically, their voluntary compliance efforts. Butzel Long has experienced attorneys to assist with your compliance program development and on-going assessment. More detail about Butzel Long's compliance counseling was recently discussed in a January 29, 2016 Client Alert.

If you have questions regarding the OIG's Guidance, compliance programs, or other health care law matters, generally, please contact your regular Butzel Long attorney, the author of this alert, or any member of Butzel Long's Health Care Industry Group.

Debra A. Geroux
248.258.2603
geroux@butzel.com