



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



OIG Enforcement Policy Statement Regarding OIG's Assessment of Advisory Opinion Requests

January 6, 2022 (Updated January 13, 2022)

Pursuant to section 1128D of the Social Security Act (the Act), the Department of Health and Human Services (HHS), through the Office of Inspector General (OIG), publishes advisory opinions regarding the application of the Federal anti-kickback statute and safe harbor provisions, as well as OIG's administrative sanction authorities, to requesting parties' proposed or existing arrangements. More specifically, in consultation with the Department of Justice (DOJ) OIG issues written advisory opinions to requesting parties with regard to: (1) what constitutes prohibited remuneration under the Federal anti-kickback statute;¹ (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Act, or established by regulation (i.e., safe harbors),² for activities that do not result in prohibited remuneration; (3) what constitutes an inducement to reduce or limit services to Medicare or Medicaid program beneficiaries under section 1128A(b) of the Act; and (4) whether an activity or proposed activity constitutes grounds for the imposition of sanctions under section 1128, 1128A, or 1128B of the Act.

OIG's advisory opinion regulations at 42 C.F.R. Part 1008 contain the specific procedures for the submission of requests by individuals or entities for advisory opinions to—and the issuance of advisory opinions by—OIG. In a final rule entitled “Procedures Regarding the Submission of Advisory Opinion Requests to, and the Issuance of Advisory Opinions by, OIG,” published on OIG's website on January 6, 2022 (the Final Rule),³ OIG revised its advisory opinion regulations to remove a procedural provision that precluded the acceptance of an advisory opinion request and/or issuance of an advisory opinion when the same or substantially the same course of action is under investigation or is the subject of a proceeding involving HHS or another governmental agency. The purpose of that regulatory provision was to prevent the advisory opinion process from interfering with the investigatory or prosecutorial authority of OIG, DOJ, or any other governmental agency. As explained in the Final Rule, OIG has removed that provision to give the agency more flexibility to issue opinions and potentially provide industry stakeholders with greater transparency regarding factors the Government may consider in evaluating compliance with certain Federal fraud and abuse laws and distinguishing between similar arrangements. Under the revised regulations, OIG will no longer be barred from issuing an advisory opinion

¹ Section 1128B(b) of the Act.

² The safe harbor regulations are set forth at 42 C.F.R. § 1001.952.

³ 87 Fed. Reg. 1367 (Jan. 11, 2022), available at <https://www.govinfo.gov/content/pkg/FR-2022-01-11/pdf/2022-00313.pdf>.

when an arrangement presented in an advisory opinion request involves conduct that is the same or substantially the same as conduct that is under investigation or subject to a governmental proceeding. The revised regulations will be effective February 10, 2022.

This policy statement is intended to clarify that the change to OIG's procedural rules gives OIG more flexibility to consider and issue advisory opinions for requests that previously would have been rejected without the opportunity for such analysis and an opinion. Consistent with current practices, OIG will continue to carefully consider the facts and circumstances of each advisory opinion request and any supplemental submissions when conducting our legal assessment of any accepted advisory opinion request. The existence of an active government investigation or other proceeding involving a Federal Government entity in connection with certain conduct could, in many circumstances, indicate that the conduct in question is suspect under the Federal anti-kickback statute or OIG's administrative enforcement authorities and subject to sanctions under section 1128, 1128A, or 1128B of the Act. Further, in some circumstances, the same or similar conduct by other parties could indicate a suspect arrangement. In the event that an advisory opinion request presents conduct that is the same or similar to conduct that is currently under investigation or subject to enforcement proceedings, that fact may indicate that the conduct in question is suspect under the Federal anti-kickback statute or OIG's administrative enforcement authorities, which would typically weigh against the issuance of a favorable advisory opinion. However, OIG will continue to review and consider all facts and circumstances of each advisory opinion request, so the fact that the same or similar conduct is currently under investigation or subject to enforcement proceedings would not necessarily be determinative with respect to the outcome of the request.

****This OIG Enforcement Policy Statement is guidance and is not binding on the agency and its personnel.**