

HOW TO REQUEST AN ADVISORY OPINION (AND WHY)

A favorable advisory opinion from the Office of Inspector General for the United States Department of Health and Human Services (OIG) ensures that the government will not impose sanctions concerning the requesting party's business arrangement. Given the highly regulated nature of the healthcare industry and the ever-present risk of enforcement, requesting an advisory opinion may be a good business decision. Stakeholders should take the following steps before, during, and after the advisory opinion process.

1. Consider your chances of obtaining a favorable opinion

OIG issues favorable opinions only when the arrangement poses no more than a minimal risk of fraud and abuse. Arrangements close to satisfying a safe harbor with appropriate safeguards are good candidates for an opinion. In some cases, even safe-harbored arrangements can make good candidates for the safety provided by an opinion. In other cases, it may make more sense to rely on OIG's analysis in similar favorable opinions.

2. Develop a plan

Submitting a proposal to OIG before undertaking the arrangement allows maximum flexibility during the advisory opinion process. Alternatively, implementing the arrangement before seeking an opinion may allow you to achieve your business goals more quickly.

3. Include all required information in your initial request

Avoid a rejection letter by referencing the advisory opinion regulations at 42 C.F.R. 1008. Include sufficient details about the parties, the arrangement, other collateral understandings, as well as operative documents and a signed certification.

4. Be transparent, and offer a persuasive argument

Demonstrate to OIG that you understand its sanction authorities and the aggravating and mitigating factors OIG frequently cites in its advisory opinions and offer clear and convincing arguments that the arrangement is not risky. Analogize and distinguish similar advisory opinions to minimize the number of OIG's follow-up questions, which can slow the process.

5. Know when to withdraw the request

If OIG determines that an opinion likely will be unfavorable, you will have an opportunity to withdraw the request. At this point, you may assume that all relevant decision-makers have reviewed the facts and agree with the conclusion. There is no right to appeal.

6. Honor the certifications post-issuance

Keep in mind that opinions are binding only on the requesting parties and only to the extent that the parties adhere to the material certifications upon which OIG relied. Deviating from the facts described in the advisory opinion might jeopardize your favorable opinion.

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