

Advisory Opinions FAQ

What is an advisory opinion?

An Office of Inspector General (OIG) advisory opinion is a legal opinion issued by OIG to one or more requesting parties about the application of the OIG's fraud and abuse authorities to the party's existing or proposed business arrangement. An OIG advisory opinion is legally binding on the Department of Health & Human Services and the requesting party or parties. It is not binding on any other governmental department or agency. A party that receives a favorable advisory opinion is protected from OIG administrative sanctions, so long as the arrangement at issue is conducted in accordance with the facts submitted to the OIG. However, no person or entity can rely on an advisory opinion issued to someone else.

What law applies to the OIG advisory opinion process?

Congress established this process as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Information about the process can be found by reviewing the following law and regulations:

Statute.

The statute is section 1128D(b) of the Social Security Act, 42 U.S.C. § 1320a-7d(b)

Regulations.

Regulations implementing the process can be found at the following locations:

- in the Code of Federal Regulations at 42 CFR Part 1008; or
- in the Federal Register by reviewing the Interim Final Rule at 62 Fed. Reg. 7,350 (1997), the Revised Final Rule at 63 Fed. Reg. 38,311 (1998), the Interim Final Rule at 73 Fed. Reg. 15937 (2008), and the Final Rule at 73 Fed. Reg. 40982(2008) (see Current Regulations).

Do I have to get an advisory opinion?

No, the advisory opinion process is voluntary. Failure to seek an advisory opinion about a transaction or business arrangement may not be introduced into evidence to prove that the party intended to violate the law.

What are appropriate subject matters for advisory opinion requests?

Most advisory opinion requests seek guidance regarding the anti-kickback statute or the anti-kickback "safe harbor" regulations. However, OIG is authorized to issue advisory opinions as to the application of the following laws and regulations:

- Anti-kickback Statute: Section 1128B(b) of the Social Security Act (SSA)
- Anti-kickback Safe Harbor Regulations: 42 CFR § 1001.952
- Exclusion Authorities: Section 1128 of the SSA
- Civil Monetary Penalty Authorities: Section 1128A of the SSA
- Criminal Penalties: Section 1128B of the SSA

A party seeking an advisory opinion can help us process its request more quickly by identifying the specific subsections of 1128, 1128A, or 1128B of the SSA about which the party is seeking an opinion and by providing facts relevant to the specific subsections.

What topics are NOT appropriate for the advisory opinion process?

We cannot address the following topics in an advisory opinion:

- hypothetical situations;
- "model" arrangements;
- general questions of interpretation;
- activities in which the party requesting the advisory opinion is not, and does not plan to be, involved (for example, we cannot issue an opinion to Company A about the business practice of Company B, unless Company A is a current or prospective party to Company B's business practice);
- the fair market value of goods, services, or property;
- whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986;
- the application of statutes not contained in sections 1128, 1128A, or 1128B of the Social Security Act (SSA);
- the application of the "Stark" law, also known as "physician self-referral law" (section 1877 of the SSA). (See Stark Law issues below.)

How do I request an advisory opinion?

You must submit advisory opinion requests in PDF format to OIGAdvisoryOpinions@oig.hhs.gov. The PDF must contain certain specified information (see the following question for additional information), including the signed certification required by 42 C.F.R. § 1008.38. If OIG accepts the advisory opinion request, all future correspondence related to the request should be emailed to the attorney assigned to the request, as designated in the acceptance letter.

What information should an advisory opinion request include?

We have prepared a checklist of the information to submit. There are also "preliminary questions" to give requestors an idea of the type of information that OIG may need to do the analysis. In general, the request must specifically identify the requesting parties (and any other actual or potential parties, to the extent known) and must provide a detailed factual description of the arrangement at issue and copies of any operative documents.

For proposed arrangements, we recognize that actual documents may not be available. In such cases, the requesting party can submit draft documents or detailed narrative descriptions of the material terms to be contained in the documents. However, material differences between the drafts or descriptions submitted and the final operative documents may affect the enforceability of the opinion.

Each requesting party must certify the truthfulness of the information submitted (see question below). We cannot issue an opinion to an anonymous requestor. You must designate a contact person who will be available to discuss your request. You may ask for an estimate of the cost for processing your advisory opinion (see question below) and/or designate a "triggering" dollar amount (see question below).

If your request contains trade secrets or confidential commercial or financial information that you believe should be protected from public disclosure, you should identify this information in the manner described in the Department of Health & Human Services' Freedom of Information Act regulations at 45 CFR § 5.41. The identification may be more effective if you designate trade secrets or confidential information contained in your request with specificity, instead of generally telling us that the request contains that kind of information.

What certifications are required?

Our regulations (42 CFR § 1008.38) provide that every advisory opinion request must include a signed certification from each requesting party using the following language, as appropriate:

For an existing arrangement:

With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health & Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.

For a proposed arrangement:

With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health & Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief. The arrangement described in this request for an advisory opinion is one that [the requestor(s)] in good faith plan(s) to undertake. [This certification may be made contingent on a favorable advisory opinion by adding the phrase "if the OIG issues a favorable advisory opinion."]

The signatory of the certification must be a person with authority to bind the requesting party. In particular, the signatory should be:

- the requesting party, if the requesting party is an individual;
- the chief executive officer or comparable officer, if the requesting party is a corporation;
- the managing partner, if the requestor is a partnership; or
- the managing member or comparable person, if the requestor is a limited liability company.

How long does it take to get an opinion?

The statute provides that advisory opinions should be issued within 60 days. In addition, the regulations establish a 10-day period for the initial review and processing of the incoming request. The length of time that it takes for the OIG to issue an opinion varies based upon a number of factors, including the complexity of the arrangement, the completeness of the submission, and how promptly the requestor responds to requests for additional information. The time frame for issuing the opinion may be extended to account for the time during which we are waiting for additional information and in certain other circumstances. We may request additional information, as needed, at any time during the processing of an advisory opinion request.

Can I withdraw my request after I've submitted it?

Yes, our regulations permit the requesting party to withdraw its request at any time before the opinion is issued. The requesting party remains liable for any fees incurred up to that point.

How much does an advisory opinion cost? Can I set a cap?

We are required by statute to collect a fee on behalf of the Treasury of the United States for preparing an advisory opinion. The statute provides no exceptions to the fee requirement. For advisory opinion requests received on or after November 8, 2016, we charge \$176 per hour for the preparation of an opinion. The actual cost of an opinion will vary based upon the amount of work required. All fees must be paid via electronic funds transfer per instructions provided by OIG. The cost of the opinion must be paid before the opinion is issued.

You can set a cap by designating a "triggering dollar amount." A triggering dollar amount is the maximum amount that you are willing to spend on an advisory opinion. If you designate a triggering dollar amount, we will stop processing your request and notify you if the costs have reached, or are likely to exceed, the amount you designate. At that point, you can withdraw the request (you remain liable for the fees incurred) or notify us that you would like us to continue processing the request. If you tell us to proceed, you will be agreeing to pay the fee even though it may exceed your triggering amount.

Can I get an estimate of the fee?

Yes, in your request you may ask for a written estimate of the cost involved in processing the advisory opinion. After our initial, 10-day review of the request, we will notify you of our estimate in writing and stop processing your request until you confirm in writing that you want us to continue. A fee estimate is not binding, and the actual cost of the opinion may be higher or lower than the estimate. Your written confirmation may include a new or revised triggering dollar amount (see How much does an advisory opinion cost? Can I set a cap?).

Will my advisory opinion be released to the public?

Yes, we are required to make opinions available to the public. (See section 1128D (b) (5) (A) (v) of the Social Security Act and 42 CFR 1008.47 of our regulations.) Advisory opinions are posted on our website. We remove identifying information, such as the names of the parties, before posting opinions on the web. In addition, information submitted in connection with an advisory opinion request may be subject to disclosure under the Freedom of Information Act (FOIA) (see What information should an advisory opinion request include?). Additional information about FOIA can be found on the OIG FOIA web page.

Will I have an opportunity to discuss my opinion request with OIG staff before it is issued?

Our goal is to render meaningful and informed opinions based on a complete and comprehensive understanding of the facts and circumstances of a given arrangement. We generally find that informal consultation with the requesting parties helps us with our review and analysis of requests. We will initiate discussions with a requesting party's designated contact person at the point at which we would find such discussions useful. We generally conduct these discussions by telephone; in-person meetings are not necessary.

Can I make changes to my proposed arrangement during the advisory opinion process?

Minor revisions to a proposed arrangement generally are not a problem, although they may delay issuance of the opinion. You will be required to submit information about the changes in writing and to certify the supplemental submission. If you need to make major changes, we may suggest that you withdraw the opinion request and submit a new one.

Does the OIG issue opinions about the "Stark" law?

Opinions about the Stark law (section 1877 of the Social Security Act; also known as the "physician self-referral law") come within the jurisdiction of the Centers for Medicare & Medicaid Services (CMS), which operates the Medicare and Medicaid programs. Information about the Stark advisory opinion process is available at 42 CFR §§ 411.370-.389.

The Stark law and the anti-kickback statute are separate statutes, and, depending on the facts, a particular arrangement might implicate one or both statutes. The Stark law applies in the case of direct and indirect financial relationships with referring physicians (as further described in that law). Although OIG is not authorized to issue opinions about the Stark law, our regulations require that a party requesting an OIG advisory opinion notify us if the party will be separately requesting a Stark opinion from CMS about the same arrangement.

I still have questions about the advisory opinion process. Whom do I call for further information?

If, after reviewing these Frequently Asked Questions and the other materials on our website, you still have questions about the advisory opinion process, you may call (202) 619-0335 and ask to speak to a member of the Industry Guidance Branch.