

Health Information Compliance Alert

Compliance: OIG Advisory Opinion Process Can Be Long, Arduous -- and Costly

The Advisory Opinion will give you peace of mind, so proceed with requesting one if you think you're on shaky ground.

If you request an Advisory Opinion --" you'll need to get ready for the realities of using the OIG's process.

Legal ramifications: Providers worry that the OIG could use the information in an Advisory Opinion request to impose penalties.

Reality: "If your Advisory Opinion concerns a proposed arrangement and the OIG issues an unfavorable opinion, the OIG generally assumes that the requester will not go through with the proposed arrangement," says **Mark Wachlin, Esq.**, a former OIG attorney who now practices with Dilworth Paxson, LLP in Philadelphia.

If your Advisory Opinion involves an existing arrangement and the opinion will be unfavorable, the OIG will normally call you and inform you that the opinion will likely be unfavorable. "The requester will then usually withdraw the advisory opinion request," Wachlin says.

"The regulations governing the advisory opinion process expressly state that in the event of withdrawal, the 'OIG reserves the right to retain any request for an advisory opinion, documents and other information submitted to it under these procedures, and to use them for any government purpose,'" Wachlin says. "In the final rule published in the Federal Register, 63 FR 38311, several commenters asked whether the 'any governmental purpose' language means that the OIG can use information submitted with requests as a basis for investigation." The OIG responded as follows:

"Our primary purpose under these regulations is to gather and assess information in order to render informed advisory opinions. However, the anti-kickback statute is a criminal statute, and therefore review of arrangements that potentially implicate the statute requires heightened scrutiny. As a law enforcement agency, the OIG cannot ignore information lawfully obtained to further legitimate governmental purposes."

Outcome: If the OIG issued an unfavorable opinion regarding an existing practice, it could pursue the requester or refer the matter to the Dept. of Justice, Wachlin says. "It is not, however, customary for this to occur. Indeed, in my three plus years at the OIG, I do not ever recall such a situation occurring."

Consider Financial Impact

If you request an Advisory Opinion, you won't get an answer overnight -- and it won't be inexpensive.

"Getting an advisory opinion is not a straightforward and simple thing -- there is a huge checklist of items that must be included with your request and the initial \$250 fee," says **David C. Harlow, Esq.** with The Harlow Group in Newton, Mass.

First, you'll pay your attorney to prepare, review, and/or submit your request. Then, after you submit it, the OIG might recommend that its independent expert review it, "and they'll engage what could be a big consulting firm or a healthcare economics firm and that cost is passed along to you," Harlow says. "Plus, they charge for staff time reviewing your case."

Keep in mind: You can set a "trigger amount," which means the OIG will contact you if they've surpassed a particular dollar amount.

Timeliness: The OIG is supposed to respond to your request within 60 days, but that doesn't necessarily start the day you

submit your paperwork. "The process could easily take six months or longer," Harlow says.

Alternative: In some cases, you might review previous Advisory Opinions and structure your arrangement to fit one that the OIG has already blessed, Harlow says.

"Whether you want to follow this path could depend on your risk tolerance," Harlow advises. "The stakes are high -- and include being barred from the Medicare program, so you don't want to guess wrong."