

OIG ADVISORY OPINION SECRETS AND STRATEGIES

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The OIG Advisory Opinion (Advisory Opinion) process allows parties of actual or proposed transactions to obtain the opinion of the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services as to whether that transaction violates the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS).

There's an official process for obtaining an OIG Advisory Opinion. Then there's the actual way that the process works. And, then there are the secrets and strategies that can be used in connection with opinions.

For decades, I considered Advisory Opinions as a set of guideposts as to how the OIG, as the primary agency charged with enforcing the federal AKS, thinks as to the application of that statute. But then I realized that there was a very different way to think of them, use them, and obtain them, which led to my work as the attorney for the Requestor of Advisory Opinion 13-15 and on many projects advising on the Advisory Opinion process and the AKS since then.

I'm going to share some of that information with you.

BACKGROUND

In order for you to grasp the dynamics of the OIG Advisory Opinion process, you first need to understand the basic elements of the AKS and its history.



In summary form, the AKS prohibits the knowing and willful solicitation, offer, payment or acceptance of any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind: (1) for referring an individual for a service or item covered by a federal healthcare program, or (2) for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item reimbursable under a federal healthcare program.

A violation is punishable as a felony: up to five years in jail, plus up to \$25,000 in fines. It can also lead to exclusion from participation in federal healthcare programs.

The AKS language is extremely broad. But what did Congress really intend to prohibit?

The AKS statute was altered by Congress many times since it was first signed into law in 1972. Its scope has

been changed. And, it hasn't always made violation a felony.

Initially, the statute was aimed at criminalizing the sort of "fee splitting" that medical ethics long prohibited. The original 1972 statutory language made violation a misdemeanor. And, it was aimed solely at Medicare and Medicaid patients, not the current, broad scope of all federal healthcare program patients. It prohibited the solicitation, offer or receipt of "any kickback or bribe in connection with" furnishing Medicare or Medicaid services or referring a patient to a provider of those services.

Over the ensuing years, there were multiple amendments as a result of industry complaints that the statute picked up more than "bad" conduct—that it criminalized behavior long considered appropriate, such as paying physicians to serve as medical directors.

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Somewhat strangely, Congress both broadened the language and, over time, enacted statutory exceptions, delegated authority to the OIG to adopt safe harbors (i.e., regulatory exceptions) and, finally, gave the OIG the power to issue Advisory Opinions.

THE ADVISORY OPINION PROCESS

The OIG is permitted to issue an Advisory Opinion upon the request of a person or organization involved in an *existing arrangement* or in an *anticipated transaction* in which the requestor in good faith plans to undertake what may be subject to AKS.

Note that the requestor's good faith in respect of an anticipated transaction may be contingent upon receiving a favorable Advisory Opinion. Distinguish this from a hypothetical query and from a general question as to interpretation, neither of which are permissible as the basis of an Advisory Opinion request.

It's also important to understand that an OIG Advisory Opinion has no application to any individual or entity that does not join in the request for the opinion, and that no individual or entity other than the requestor(s) may legally relay it.

Both the regulations pertaining to Advisory Opinions and the checklists provided by the OIG outline the information required to be provided to the OIG and the costs of an opinion. For purposes of this article, be aware that the request has to be in writing and that among the information that must be provided is:

What I call the "who" information:

1. The name and addresses of the requestor and all other actual and potential parties to the extent known to the requestor.
2. The name, title, address and day-time telephone number of a contact person.
3. Each requesting party's Taxpayer Identification Number.
4. Full and complete information as to the identity of each entity owned or controlled by the individual, and of each person with an ownership or control interest in the entity.

What I call the "what" information:

1. A complete and specific description of all relevant information bearing on the arrangement and on the circumstances of the conduct.
2. All relevant background information.
3. Complete copies of all operative documents, if applicable, or narrative descriptions of those documents. For existing arrangements, that means complete copies of all operative documents. For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts or models of documents sufficient to

permit the OIG to render an informed opinion.

4. Detailed statements of all collateral or oral understandings (if any).

And, then there's the certification:

The request must include a signed certification that all of the information provided is true and correct and that it constitutes a complete description of the facts regarding which the Advisory Opinion is sought.

TIMELINE

Once the OIG accepts the request and assigns the file to an attorney in their office, the OIG has 60 days to issue an opinion.

However, the acceptance process and the OIG's right to request additional information from the requestor can result in significant delay in the 60-day countdown.

In general terms, the OIG has the right to request additional information both before and after a request is accepted. The time between a request and the receipt of the response stops the clock. Additionally, the delivery of additional information to the OIG prior to the date of acceptance re-starts the entire process in terms of timing.

It's not uncommon for the process to play out over the course of many, many months.

WAYS ADVISORY OPINIONS CAN BE USED STRATEGICALLY

Now that you have some background information, let's shift gears and address a few of the ways that Advisory Opinions can be used strategically, as well as some of the strategies and tactics used in the opinion process.



Warning!

In consulting in connection with Advisory Opinions, I often see a strategic mistake about to be made by requestors and their counsel: they approach the process as a mere presentation of the facts and then plan to sit waiting for the opinion.

That's as far from the correct approach as penguins are from the North Pole.

Conducted properly, a request for an OIG Advisory Opinion is an argument designed strategically and psychologically to bring the OIG toward your conclusion. Its prosecution requires skill, strategy and diplomacy; absent any, you are creating an outsized risk.

As mentioned above, the Advisory Opinion process allows for significant follow-up and ongoing contact. Sure, you could just lay low and perhaps hide or just hope the conclusion is going to come out as you want it. But there's a process that allows you to have continuing input, and you should use it to your advantage, taking every opportunity to trigger additional conversations with the assigned OIG attorney.

But this leads to a more basic question: why are you requesting an Advisory Opinion? What's the reason?

Why?

My guess is that most requestors are seeking an actual opinion to which they want a "yes" response, that is, a positive Advisory Opinion. I believe that that is what Congress imagined—that people would seek a positive opinion. I call this a "may I" or a "should I have?" request.

May I?/Should I have?

For example, a requestor might seek an opinion on the propriety of the use of a "preferred hospital" network as part of Medigap policy, whereby the Requestors, which offer Medigap policies, would contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for their policyholders and, in turn, would provide a premium credit of \$100 to policyholders who use a network hospital for an inpatient stay. Those are the facts in Advisory Opinion 16-01.

Or we can translate this into an anesthesia example. A hospital might approach your group with the proposition that, upon renewal of its exclusive contract, the group will take on much more intense administrative duties, while at the same time suffering a cut in the administrative stipend received from the hospital.

Please tell me I shouldn't have . . .

There's a second category that I call "please tell me I shouldn't have" and this is neither as obvious nor as straightforward. You use it to attempt to unwind a deal you were forced into.

For example, your group has been providing services at a surgery center for several years and has been paying the facility rent for office space within to complete the anesthesia record and for sitting between breaks in cases. The ASC administrator assures you it's legal and says that it wouldn't alter the relationship if it's not. So you turn to the OIG for an opinion. You hope that it's negative in order to bow out of the relationship gracefully or to restructure it.

Other Categories

There are other, more sophisticated categories as well, including blocking tactics, leverage tactics and triangulation tactics, each of which is beyond the scope of this article, but each of which should be considered in connection with your compliance efforts, and even more importantly, in connection with your offensive as well as defensive competitive efforts.

Bottom Line

You should now have an appreciation for how the process should be used as a part of advocacy. Requests are NOT the equivalent of an essay contest in which the judge takes a look at each submission and makes a yes or no decision.

In fact, if you want to analogize to a contest, it's more like one of those cooking challenge shows on the Food Network where the contestants battle to tell the most politically correct story of what they'll do with the money if they win.

That story impacts taste, just like your story may very well impact the outcome of a request for an Advisory Opinion. Tell a good story and use every opportunity to drive the point home. ▲



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