July 18, 2022
Volume XII, Number 199

THE
NATIONAL LAW REVIEW

OIG Removes Barrier to Requests for and Issuances of Advisory Opinions When the Same Conduct is Under Investigation

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Monday, February 7, 2022

On January 11, 2022, the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) issued, without an opportunity for public notice and comment,[1] a Final Rule, amending its internal process for accepting and issuing advisory opinions. 87 Fed. Reg. 1367 (Jan. 11, 2022). In response to the industry's "expressed frustration" with the regulatory provision precluding advisory opinion requests from being accepted and/or advisory opinions from being issued when the same conduct is under investigation by a governmental agency, OIG decided to remove that barrier altogether, effective February 10, 2022. Id. at 1368. OIG's amendment is surprising, since OIG did not publicly signal its intent to make such a change and because the Final Rule is not simply procedural in nature. It is unclear whether OIG's well-intended amendment will have any meaningful upside for requestors of advisory opinions.

The current regulation, which substantively has been in effect since OIG issued its 1997 interim final rule (as finalized in 1998 and amended in other aspects in March 2008 and July 2008), precludes an advisory opinion request from being accepted and/or an advisory opinion from being issued when the same or substantially the

subject of a proceeding involving HHS or another governmental agency." Id.

Within the current regulatory framework, a requestor seeking an advisory opinion receives notice of OIG's formal declination to accept the request for an advisory opinion. 42 C.F.R. § 1008.41(b)(3). However, when such notice is provided, OIG does not appear to have any obligation or responsibility to inform the requestor why. Id. at Part 1008, in passim. This appears to be the likely source of the "expressed frustration" OIG addresses in its Final Rule.[2] Indeed, if OIG rejects a request for an advisory opinion under 42 C.F.R. § 1008.15(c)(2) because, e.g., the matter under investigation by DOJ is under seal, OIG is not permitted to disclose that reason to the requestor. Consequently, requestors have been left wondering why they were precluded from receiving advisory opinions.[3]

Now, the barrier to having an advisory opinion request accepted and an advisory opinion issued in these circumstances has been knocked down—by OIG itself. In its Final Rule, OIG explained its two-fold reasoning for making such a change as (1) offering OIG more flexibility in responding to requests for advisory opinions and in issuing favorable or unfavorable[4] advisory opinions when an arrangement presented in a request involves conduct that is the same or substantially the same as conduct that is under investigation or subject to a proceeding, and (2) providing 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. 87 Fed. Reg. at 1368. It is unclear, however, whether this new regulatory framework will ultimately benefit requestors.

On the one hand, a requestor can rest assured that its request for an advisory opinion will not be declined on the basis that the same, or substantially the same, course of action is under investigation by, or is or has been the subject of a proceeding involving, any governmental agency. That basis is now unavailable to, and not required to be used by, OIG, effective February 10, 2022. If the request for an advisory opinion is accepted and the same conduct is under investigation by, e.g., DOJ, the requestor could presume that DOJ, via its "consultation with" OIG and via OIG's requests for additional information from the requestor during its ordinary process of fact-gathering, would not use OIG's advisory opinion process as an extension of its investigatory authority. 42 C.F.R. § 1008.1(a); id. at § 1008.39. Likewise, the requestor could also presume that OIG would not permit DOJ to engage in such investigatory conduct through OIG's advisory opinion process.

On the other hand, it is unclear how OIG could feasibly issue a favorable advisory opinion related to conduct that is concurrently under investigation by DOJ. Indeed, OIG even admits this would be unlikely: "[I]f the arrangement for which an advisory opinion is sought is the same or similar conduct that is currently under investigation or is the subject of a proceeding involving a governmental agency, that fact will weigh against the issuance of a favorable advisory opinion because such circumstances generally indicate that the arrangement does not present a sufficiently low risk of fraud and abuse." 87 Fed. Reg. at 1368 (emphasis added). However, OIG's sentiment may presume too much.

First, OIG appears to presuppose that any conduct under investigation by DOJ—by virtue of it being under investigation—is problematic. To the contrary, conduct under investigation by DOJ has merely been alleged to be problematic. Even if DOJ resolves such conduct via, e.g., settlement agreement, there is no admission of liability by the individual or entity that has allegedly engaged in such "problematic" conduct. But, if OIG issues an unfavorable advisory opinion, such a conclusion could provide a sufficient basis for DOJ to proceed with its investigation or even intervene in a qui tam action. Additionally, even if OIG is prepared to issue an unfavorable advisory opinion and the requestor "withdraw[s] [its] request prior to the issuance" of such advisory opinion

requestor for the conduct. Id. at § 1008.1(d).

Second, a question emerges: What does a favorable advisory opinion mean for both the requestor and DOJ under the new regulatory framework? Certainly, if OIG "blesses" conduct that is also under investigation by DOJ, one could presume that DOJ would not likely move forward with its investigation for that conduct. Indeed, in such circumstances where DOJ decides to move forward and, e.g., intervene in a qui tam action notwithstanding a favorable advisory opinion related to that same conduct, the requestor could, and probably should, attach that favorable advisory opinion as "Exhibit 1" to its answer.

Lastly, regardless of whether OIG issues a favorable or unfavorable advisory opinion related to the same or substantially the same conduct that is under investigation by another governmental agency, it is unclear how OIG's removal of the barrier will interact with OIG's other regulatory limitations affecting the industry. For example, if a requestor receives a favorable advisory opinion related to a set of facts and circumstances that may not necessarily be unique to the requestor itself, the applicable regulations would still prohibit another individual or entity's reliance on or use of such favorable advisory opinion as evidence during litigation. Id. at § 1008.53 ("No individual or entity other than the requestor(s) may rely on an advisory opinion."), id. at 1008.55 ("An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate" the law reviewed by OIG in the advisory opinion.). If such facts and circumstances were under investigation by DOJ, but the investigation related to an individual or entity that is not the requestor, presumably OIG's issuance of a favorable advisory opinion would, and should, give DOJ pause. Indeed, DOJ, in consideration of its investigation into the same or similar conduct, would presumably re-consider continuing with such investigation.

On balance, OIG's removing the barrier to advisory opinion requests being accepted and/or advisory opinions being issued when the same or similar conduct is under investigation by a governmental agency, such as DOJ, may not benefit, and could end up harming, requestors because (1) the likelihood that a favorable advisory opinion will be issued by OIG when that conduct is under investigation by DOJ is low, (2) an unfavorable advisory opinion may affect DOJ's investigation into the conduct adversely to the requestor, and (3) any information provided by the requestor to OIG at OIG's request during the advisory opinion process may be shared with DOJ, even when DOJ is investigating the conduct.

FOOTNOTES

[1] In its Final Rule, OIG explains that, "[b]ecause this rule is procedural, notice and comment rulemaking is not required under 5 U.S.C. 553(b)(A)"—i.e., the Administrative Procedure Act. 87 Fed. Reg. at 1368.

[2] OIG explains how it "reject[s] advisory opinion requests pursuant to the existing regulation," but does not indicate whether it actually informs the requestors the reason for such rejections. Id. (emphasis added).

[3] Even so, savvy requestors could reasonably deduce whether their requests for advisory opinions have been declined based on the other factors set forth at 42 C.F.R. 1008.15.

[4] A "favorable opinion" describes an advisory opinion when OIG has determined that either (1) the arrangement would not violate the law and would not constitute grounds for the imposition of sanctions under that law, or (2) even if an arrangement would violate the law, OIG would not impose administrative sanctions on a requestor under that law in connection with the arrangement. See e.g., Advisory Opinion 21-10 as an example of the former, *available at* Advisory Opinion 21-10 | Office of Inspector General | Government Oversight | U.S.

Opinion 21-18 | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov).

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