

STAKEHOLDERS ASKED AND CMS LISTENED - AGENCY PROPOSES TO MODIFY STARK LAW ADVISORY OPINION PROCESS

In the recently issued Physician Fee Schedule Proposed Rule for Calendar Year 2020, the Centers for Medicare & Medicaid Services ("CMS") proposed several revisions to its Stark Law advisory opinion process. These proposed revisions follow CMS's receipt of several stakeholder comments in response to its Request for Information Regarding the Physician Self-Referral Law published on June 25, 2018. CMS did not specifically solicit comments regarding the advisory opinion process but, due to the response received, has decided to propose the following revisions.

CMS's advisory opinion process relates solely to inquiries pertaining to the permissibility of arrangements under the Physician Self-Referral Law (commonly referred to as the Stark Law). Historically, CMS's advisory opinion process has been utilized much less frequently by stakeholders than the Office of Inspector General's ("OIG's") advisory opinion process for arrangements implicating the Anti-Kickback Statute and/or the Civil Monetary Penalties Law.

PROPOSED REVISIONS

1. CMS has proposed to add additional reasons why it will not accept advisory opinion requests. If an advisory opinion request does not include sufficient detail and the requestor fails to respond timely to CMS's requests for additional information, CMS will not issue an advisory opinion.
2. Currently, CMS will not issue an advisory opinion if it is aware that substantially the same course of action is under investigation or involved in a proceeding with a governmental agency. CMS has proposed to modify this restriction to provide it with discretion regarding how to move forward with such advisory opinion requests after CMS has consulted with OIG and/or Department of Justice.
3. CMS has proposed a 60-day time frame to issue an advisory opinion. This time period begins once the submission has been formally accepted for review. The time period is tolled during periods in which CMS is waiting for additional information from the requestor and/or the requestor is revising the advisory opinion request. The current time frame for the issuance of an advisory opinion is 90 days.
4. Currently, CMS requires that advisory opinion requests be signed and certified by the requestor's Chief Executive Officer or comparable officer, managing partner or managing member (depending upon organization type). CMS has proposed to clarify that the certification must simply be signed by an officer that is authorized to act on the requesting entity's behalf. It is also seeking comment regarding whether the certification requirement should be eliminated.
5. CMS has proposed modifying its current initial fee of \$250 plus additional costs incurred to an hourly rate for the preparation of the advisory opinion. It has proposed to charge \$220 per hour for standard turnaround advisory opinions. CMS has further proposed an hourly rate of \$440 for the preparation of expedited advisory opinion requests. It is seeking comments regarding whether or not there should be a cap on the amount of fees that can be charged for an advisory opinion.
6. CMS is considering providing third parties with greater comfort when relying on advisory opinions by proposing that it will not impose sanctions against entities that enter into arrangements that it determines to be indistinguishable from arrangements that were subject to favorable advisory opinions. In addition, it has proposed that entities may reasonably rely on advisory opinions as non-binding guidance.

ADDITIONAL COMMENTS SOLICITED

In addition to seeking input from stakeholders with respect to the proposed revisions described above, CMS has also solicited comments on several other aspects of the advisory opinion process:

- Despite requests from stakeholders, CMS did not propose to expand the scope of the requests it considers for the advisory opinion process. However, it has solicited comments on whether it should expand the scope of the advisory opinion process in the future.
- CMS has also solicited comments regarding whether or not there should be an expedited advisory opinion review process for requests

that meet certain criteria. It has proposed that there would be a 30-day turnaround for expedited requests. In addition, it has requested stakeholder input regarding what parameters should be required for a request to qualify for expedited review.

- Lastly, CMS has solicited comments regarding whether it should retain more limited rights to rescind advisory opinions, such that it could only rescind an advisory opinion if there was a material regulatory change that impacted the conclusion that had been reached or if a party wished to have CMS reconsider a prior advisory opinion in light of new circumstances or laws.

Comments on the proposed modifications to the Stark Law advisory opinion process are due no later than 5:00 PM E.T. on September 27, 2019.

This alert is brought to you by Hall Render's **Fraud and Abuse** Service Line. If you would like additional information about this topic or would like assistance with submitting comments to CMS, please contact:

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