PUBLICATION

CMS Proposes Liberalizing the Stark Advisory Opinion Process

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When the Centers for Medicare and Medicaid Services (CMS) sought input on ways to address the undue burdens of the Stark law through a Request for Information (RFI) in June 2018, its anticipated focus was care coordination, not necessarily the advisory opinion process. So many stakeholders commented on the current process, however, that CMS has proposed changes to the advisory opinion regulations, codified at 42 CFR §§ 411.370 through 411.389. The proposed rule, issued July 29, 2019, aims to liberalize CMS's process for issuing advisory opinions on the application of the Physician Self-Referral (Stark) law.

In the proposed rule, CMS acknowledges that its advisory opinion regulations, which were modeled after the Office of the Inspector General's (OIG) regulations, were aimed at interpreting laws that were distinct from the OIG's. The agency further states that there are several differences between the anti-kickback provisions and the Stark provisions that make it reasonable to have different advisory opinion regulations and processes. CMS identifies the following distinctions between the Stark provisions and the Anti-Kickback Statute:

- The Stark law is a strict liability law requiring certainty, while the Anti-Kickback Statute is a criminal statute focused on prosecuting intentional acts of fraud and abuse.

- Arrangements that do not fit squarely within an anti-kickback safe harbor would not necessarily violate the Anti-Kickback Statute; however, the Stark provisions do not offer the same privilege. A financial arrangement that does not fit squarely under a Stark exception violates the statute, regardless of the parties' intent or good faith. CMS therefore recognizes that the failure to clearly understand the Stark law carries significant penalties.

- CMS can only issue favorable advisory opinions for arrangements that do not violate the Stark law, because its advisory opinion authority is narrowly tailored. The agency explains that it cannot extend protections beyond the Stark law exceptions regardless of the circumstances surrounding an arrangement. On the other hand, the OIG has issued favorable advisory opinions based on the totality of the facts and circumstances surrounding an arrangement (including allowed risk of fraud and abuse), even when the arrangement does not fit within a safe harbor.

CMS further shares that the current stringent advisory opinion process has dissuaded stakeholders who would have otherwise requested advisory opinions. The agency states, "We have reviewed our advisory opinion regulations in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process." To remedy these issues and address stakeholder responses to the RFI, CMS proposes the following changes to the advisory opinion regulations.

1. *Failure to issue an advisory opinion*. CMS proposes to amend § 411.370(e) to clarify when the agency may decline to issue an advisory opinion. Specifically, CMS states that it will deny a request for an advisory opinion where the requestor does not describe the arrangement with a level of detail necessary for CMS to issue an opinion and where the requestor does not timely respond to CMS's request for additional information.

2. ***Simultaneous Investigations***. CMS proposes to amend § 411.370(e)(2), which currently states that "CMS will not issue an advisory opinion if it is aware that the same, or substantially the same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities." According to the agency, the current regulations are restrictive and delay guidance to requestors. CMS proposes to change this section to read that CMS "may elect not to accept an advisory opinion request or issue an advisory opinion" after consultation with the DOJ and OIG.

3. ***Timeline for issuing advisory opinions***. CMS proposes to decrease the timeline for issuing advisory opinions from 90 days to 60 days. The 60-day period begins on the date CMS formally accepts the request for an advisory opinion and will be tolled during time periods where the request is being revised or additional information is being compiled and presented by the requestor.

4. ***Expedited advisory opinions***. CMS also proposes to include a provision in the regulations for expedited reviews. The agency understands that some issues require an urgent response and would like to provide this option to stakeholders. CMS asks stakeholders for comments regarding the parameters for such reviews.

5. ***Burdensome Certification Requirements***. CMS proposes to remove the certification requirements at § 411.373(a) and (b), under which the requestor must certify that, to the best of the requestor's knowledge, the information provided is true and correct and a complete description of the facts. If the request relates to a proposed arrangement, the requestor must certify that it intends in good faith to enter into the arrangement described. The agency recognizes that the current certification requirements are burdensome and redundant "given that section 1001 of Title 18 of the United States Code [already] prohibits material false statements in matters within the jurisdiction of a federal agency."

6. ***Increased fees for advisory opinions***. Under the current regulations, a requestor must pay an initial fee of $250 and any additional costs incurred above the initial $250 payment. CMS proposes to adopt a $220 per hour fee for the preparation of an advisory opinion, with a set maximum cap. CMS also proposes a charge of $440 per hour for expedited advisory opinion, if the agency adopts an expedited advisory opinion provision as proposed. CMS requests comments regarding the proposed cap amount and whether or not it should cancel the initial $250 fee.

7. ***Reliance by third parties***. CMS proposes expanding the group of individuals who may rely on an advisory opinion. Currently, CMS regulations, which are modeled after the OIG advisory opinion regulations, preclude reliance by third parties. CMS explains that such preclusion may be appropriate for an OIG advisory opinion which examines a criminal statute and takes into account the circumstances surrounding an arrangement and the intent of the parties. However, such requirements may be unduly restrictive for a "strict liability payment rule that applies regardless of a party's intent." CMS proposes that "individuals or entities that are parties to the specific arrangement" and "individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion," may rely on its advisory opinion.

8. ***Reliance by the General Public***. CMS proposes to amend § 411.387(c) to recognize that the public may reasonably rely on an advisory opinion as "non-binding guidance" on the interpretation of the Stark law and regulations. CMS is aware that stakeholders already rely on the advisory opinions in this manner and it acknowledges that such reliance is "permissible and reasonable."

9. ***CMS's Rescission Authority***. CMS has a broad authority to rescind or revoke advisory opinions. The agency proposes to limit its rescission authority to "only when there is a material regulatory change that impacts the conclusions reached, or when a party has received a negative advisory opinion and wishes to have the agency reconsider the request in light of new facts or law."

The proposed rule discusses other minor modifications to improve the readability and clarity of the advisory opinion regulations. These proposed changes may provide more helpful and timely guidance from the agency. However, time will tell whether CMS is in a position to operationalize the changes, particularly given the current timing of Stark self-disclosures. Comments on the proposed rule are due to CMS by September 27, 2019.

For more information, please contact any member of Baker Donelson's Health Law Reimbursement Group.