PUBLICATION

CMS Improves Stark Advisory Opinion Process

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The Centers for Medicare & Medicaid Services (CMS) recently updated its advisory opinion regulations, codified at 42 CFR §§ 411.370 through 411.389, in a final rule issued November 15, 2019. The update liberalizes and improves CMS's process for issuing advisory opinions on the application of the Physician Self-Referral (Stark) Law. The proposed changes and final rule to the advisory opinion process stem from the volume of comments the agency received through a June 2018 Request for Information (RFI). Although the RFI was for input on care coordination, many stakeholders took the opportunity to note the inadequacies of the current advisory opinion process.

CMS heard these concerns and made the following meaningful changes to the advisory opinion process, in addition to minor modifications to improve clarity.

Reliance on Advisory Opinions (§ 411.387)

CMS expanded the scope of individuals who may rely on an issued advisory opinion. Under the current rules, only the requestors of an advisory opinion may rely on that specific advisory opinion and non-requestor third parties were precluded from relying on any issued advisory opinion. Under the new rules:

The advisory opinion will be binding on the Secretary of Health and Human Services (HHS). In addition, when CMS issues a favorable opinion, the Secretary of HHS may not impose sanctions, under the Stark Law, on the parties that requested the opinion or the individuals or entities that are parties to the specific arrangement. CMS recognized that the parties to the arrangement relied on the opinions even if they did not join in the request for the advisory opinion.

The Secretary of HHS will not bring sanctions under the Stark Law against any individuals or entities that are parties to an arrangement that CMS determines is "indistinguishable in all material aspects" from an arrangement for which CMS issued a favorable advisory opinion. However, CMS notes that facts that influence a legal conclusion in an advisory opinion are material. Parties can ask CMS for a determination on whether an arrangement is indistinguishable in all material aspects.

Individuals and entities may now reasonably rely on an advisory opinion as non-binding guidance that illustrates the application of the Stark Law to specific facts and circumstances. Interestingly, CMS notes that stakeholders already use the advisory opinions to inform their decision making. The final rule also states that Accountable Care Organization (ACO) participants can rely on an advisory opinion as non-binding guidance, even when their ACO arrangement is "substantially similar to but not the same as the arrangement that is the subject of the advisory opinion."

Notably, CMS makes it clear that a reasonable reliance on an advisory opinion is not sufficient to defeat a claim under the False Claims Act.

Timeline for Issuing Advisory Opinions (§ 411.380)

The new final rules change the current advisory opinion timeframe from 90 days to 60 "working" days. The 60 working days' time period will begin on the date that CMS formally accepts a request for review. The agency will *formally accept a request for review* when it determines that "(a) the request and any supplemental submissions describe the arrangement at issue with a level of detail sufficient for CMS to issue the opinion, and (b) the grounds for rejection of a request listed at § 411.370(e) do not apply." CMS will still maintain its additional 15-working-days review period to determine whether the submission sufficiently describes the arrangement.

The final rule also implements an expedited advisory opinion process. However, this expedited process is limited to requestors who wish to determine whether an arrangement is indistinguishable in all material aspects from another arrangement CMS has found complies with the Stark Law. The expedited review period will be 30 working days.

Advisory Opinion Fees (§ 411.375)

Under current Stark regulations, a requestor must pay an initial fee of $250 and may then designate a triggering dollar amount which would cause CMS to notify the requestor if the agency estimates that the costs of processing the advisory opinion has reached or would likely exceed the designated triggering amount. The final rule disposes of the initial $250 fee and implements a $220 hourly rate for advisory opinion requests. Although the proposed rule considered a $440 hourly rate for expedited reviews, CMS will no longer implement such a fee. CMS explained that the $440 fee was initially proposed for expedited advisory opinions because it envisioned it would be opining on complex matters within a short period of time. However, the $440 fee is no longer needed because the expedited review pathway would only apply to very limited types of requests, namely determinations on whether an arrangement is indistinguishable in all material respects to another arrangement that is the subject of a favorable advisory opinion. CMS envisions that these types of opinions will be very straightforward and non-complex.

In an effort to address the cost concerns raised by smaller and rural providers, CMS will consider providing cost estimates for the advisory opinion; potential discounts, on a case-by-case basis, for requestors with demonstrated limited financial resources; or possibly capping the total charges for an advisory opinion.

Matters Subject to Advisory Opinions (§ 411.370)

CMS further clarifies situations in which it would accept a request to issue an advisory opinion.

The agency clarifies that it would consider advisory opinion requests on questions that "relate to" existing or planned arrangements, rather than only those that "involve" existing or planned arrangements.

CMS reiterates that requests regarding hypothetical facts or general questions of interpretation are not appropriate for an advisory opinion. In order to limit the confusion related to CMS's distinction between a planned arrangement and a hypothetical fact pattern or question of general interpretation, CMS has removed the differentiating language from the regulations. CMS also has modified the regulations to reflect that it would not issue advisory opinions for instances where "the underlying financial arrangement between the physician and the entity to which he or she refers designated health services is otherwise illegal or impermissible." For example, CMS will deny an advisory opinion request asking whether a physician referral is permitted where the claim for the designated health services could not be billed to the Medicare program for reasons unrelated to the Stark Law. CMS also emphasizes that the requestor must provide sufficient detail about the arrangement and the parties to the arrangement, including providing information about one or both of the parties to the arrangement.

In addition, CMS has relaxed its stance on not accepting requests for advisory opinions on arrangements with the same or substantially the same course of action under investigation or that is subject to an HHS or other government agency proceeding. Under the modified rules, CMS "may elect not to accept an advisory opinion request or issue an advisory opinion if, after consultation with OIG and DOJ, it determines that the course of action described in the request is substantially similar to conduct that is under investigation or the subject of a proceeding" involving HHS or another agency.

Certification (§ 411.373)
The final rule now allows any authorized officer of a corporation, in addition to the Chief Executive Officer of a corporation, to sign the certification statement.

Rescission (§ 411.382)
Under the current rules, CMS could rescind or revoke an advisory opinion if it determines that it is in the public interest to do so. The new rules state that CMS may rescind an advisory opinion for good cause. Good cause exists when "(i) there is a material change in the law that affects the conclusions reached in an opinion; or (ii) a party that has received a negative advisory opinion seeks reconsideration based on new facts or law." The amendment to the rule will also require CMS to provide advance notice to the requestor and the public.

Takeaway
While stakeholders have generally looked to the CMS advisory opinions for guidance, only the requestor of an opinion could rely on and be protected by that opinion. With the updated regulations, CMS has expanded the scope of individuals who may rely on the advisory opinions as binding guidance and provided a process for non-requestors to seek a determination from CMS on whether an arrangement is indistinguishable in all material aspects from one which is the subject of an opinion issued to another individual or entity. In addition, CMS clarified and expanded the scope of advisory opinion requests it will accept that relate to existing or planned arrangements. With these meaningful changes to the advisory opinion process, we expect stakeholders will be more inclined to use the opinion or determination process to confirm their existing or planned arrangements are compliant with the Stark Law requirements.