

CMS Finalizes Changes to the Stark Advisory Opinion Regulations; 2020 DHS Code List and CPI-U Updates

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In the calendar year 2020 Medicare physician fee schedule final rule (“PFS”), which was published in the Federal Register on November 15, 2019 (available [here](#)), CMS finalized changes to the advisory opinion process under the federal physician self-referral law (“Stark Law” or “Stark”). CMS also published its annual update to CPT/HCPCS codes used to identify certain categories of Stark designated health services (or “DHS”). These regulatory changes and annual code update both go into effect on January 1, 2020.

Finalized Changes to Stark Advisory Opinion Regulations

Under the CMS advisory opinion process, the regulations for which are found at 42 C.F.R. §§ 411.370–389, parties can seek an advisory opinion from CMS as to whether a referral for DHS (other than clinical laboratory services) is prohibited under the Stark Law. CMS determines in the opinion whether an arrangement constitutes a “financial relationship” that would implicate the Stark Law’s referral prohibition and whether the arrangement or the referred service qualifies for a Stark Law exception. CMS issued a Request for Information (“RFI”) in June 2018 as part of the “Regulatory Sprint to Coordinated Care” about ways CMS could modify the Stark Law regulations in order to reduce barriers to patient care coordination and value-based arrangements and to reduce the regulatory burden of complying with the Stark Law generally, which we wrote about [here](#). CMS did not specifically solicit comments regarding the Stark advisory opinion process in the RFI, but CMS received a number of comments about ways that the Stark advisory opinion process could be improved. CMS explains in preamble to the PFS that it “undertook a fresh review” of the advisory opinion process in light of the comments it received to “identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process.”

CMS also recently issued sweeping proposed Stark Law regulatory changes as part of the Regulatory Sprint to Coordinated Care on topics related to the RFI, which we wrote about in a white paper available [here](#). While the changes to the advisory opinion regulations do not directly relate to the shift to a value-based health care delivery system,

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CMS acknowledges in preamble to the PFS that “a faster and more robust advisory opinion process facilitates the shift to value-based care arrangements by providing more guidance for parties trying to understand how the physician self-referral law applies in an evolving and innovative marketplace. This will help to reduce provider burden by providing insight into what does and does not comply with the law, which encourages innovation.”

Since the initial advisory opinion regulations were issued in 1998, CMS has only issued 16 advisory opinions, which are available [here](#). (CMS also issued 15 advisory opinions from 2004-2005 during the 18-month moratorium on physician ownership and investment interests in specialty hospitals that was in effect at that time, which are available [here](#).) In contrast, the Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”), which has a separate advisory opinion process for the federal anti-kickback statute (“AKS”) and certain other laws, issued 14 advisory opinions in calendar year 2018 alone (available [here](#)). In preamble to the PFS, CMS recognizes the importance of an accessible advisory opinion process and acknowledges that the current advisory opinion process has not been widely used. An accessible advisory opinion process is particularly important in the context of the Stark Law, since it is a strict liability statute, and there is a great need for certainty because, as CMS acknowledges, “parties that act in good faith may nonetheless face significant financial exposure if they misunderstand or misapply the law’s exceptions.”

We anticipate that the changes to the advisory opinion process may indeed help to make the process more meaningful and accessible to entities that are seeking to understand if their arrangement complies with the Stark Law, particularly due to CMS’s

broadening of how advisory opinions can be relied upon (as described below). *If you are interested in submitting an advisory opinion request, or for advice on whether and how you can rely on a published advisory opinion in assessing an arrangement for compliance with the Stark Law, please contact the authors or your regular Dorsey attorney.*



The most notable changes to the advisory opinion regulations in the PFS are the following:

- **Reliance on an Advisory Opinion:** Under existing Stark regulations, only the individual or entity that requested the advisory opinion may rely on the opinion. In the PFS, CMS finalizes revisions to regulations to specify the following:
 - An advisory opinion is binding on the Secretary of HHS, and a favorable advisory opinion means that sanctions will not be imposed under the Stark Law with respect to individuals/entities that are *parties to the arrangement* upon which the opinion was issued (as well as the individuals/entities that requested the opinion).
 - The Secretary of HHS will not pursue sanctions under the Stark Law “against any

party to an arrangement that CMS determines *is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.*” Parties can submit an advisory opinion request to determine whether CMS would view their arrangement as “indistinguishable in all material aspects” from another arrangement that has received a favorable opinion, which will be issued by CMS on an expedited basis (as explained below).

- Individuals/entities can rely on advisory opinions “as *non-binding guidance that illustrates the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.*” CMS acknowledges that stakeholders already use advisory opinions to inform their decision-making, and this change is intended to make clear that “such reliance is permissible and reasonable.”
- Timeline for Issuing an Advisory Opinion:
 - Under existing regulations, CMS currently has a 90-day timeframe to issue an advisory opinion. CMS finalizes its proposed changes to the regulatory text to shorten this to 60 “working days” (where “working day” excludes weekends and holidays) after the request has been formally accepted. CMS maintains the discretion it has in existing regulations to extend this time period when a request involves “complex legal issues of first impression or highly complicated fact patterns” and to suspend the time period in certain circumstances.
 - CMS finalizes revisions to regulations to provide for expedited review of advisory opinion requests that relate to whether an arrangement is “indistinguishable in all material aspects” from an arrangement that was the subject of a favorable advisory opinion. The expedited review period will be 30 working days.
- Fees for the Cost of Advisory Opinions: CMS finalizes revisions to regulations to revise the fee structure for advisory opinions. Specifically, the \$250 initial fee is removed and a \$220 hourly rate is implemented.

In the PFS, CMS also finalizes its proposed changes to the advisory opinion regulations in the following areas (among others):

- Matters Subject to Advisory Opinions:
 - CMS finalizes revisions to regulations to allow CMS to consider advisory opinion requests that “relate to” existing or planned arrangements, rather than requests that “involve” them, which is intended to capture the scope of appropriate advisory opinion requests.
 - CMS explains that it remains its position that advisory opinion requests cannot be regarding only “hypothetical facts or general questions of interpretation,” but must be about a specific referral, physician, financial relationship and facts/circumstances. CMS does acknowledge, however, that there is some confusion over what is a *planned* arrangement versus a *hypothetical* arrangement, so is removing this language from the advisory opinion regulations. It also revised the regulatory text to reflect its view that a request for an advisory opinion would not be accepted if the claim could not be billed to Medicare for some reason unrelated to the Stark Law.
 - CMS finalizes revisions to regulations to allow CMS more flexibility related to advisory opinion requests that involve conduct that is “substantially similar to conduct that is under investigation or is the subject of a law enforcement proceeding.”

- **Certification Requirement:** CMS finalizes revisions to regulations to allow for any authorized officer of the corporation to sign the certification statement, in addition to the Chief Executive Officer.
- **Rescission:** CMS finalizes revisions to regulations related to when CMS may rescind an advisory opinion, which is when CMS determines that there is good cause to do so. “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.” CMS declines to adopt a minimum wind-down period in regulatory text for arrangements that are the subject of a rescinded advisory opinion, and states that it will work with parties affected by a rescinded opinion to determine a reasonable wind down period. CMS also finalizes regulatory changes to provide for an advance notice to the requestor and the public of a rescinded opinion.

2020 DHS Code List and CPI-U Updates

The PFS also includes the annual update to the list of CPT/HCPCS codes used to identify certain categories of DHS (the “Code List”). As we explained in prior posts (such as [this one](#)), the Stark Law regulations at 42 C.F.R. § 411.351 specify that the following four categories of DHS are defined by reference to the Code List: (1) clinical laboratory services; (2) physical therapy, occupational therapy, and outpatient speech-language pathology services; (3) radiology and certain other imaging services; and (4) radiation therapy services and supplies. The Code List is updated annually to reflect changes in the most recent CPT and HCPCS Level II publications.

Further, items and services that may qualify for either of two Stark Law exceptions—the exception for preventive screening tests, immunizations and vaccines at 42 C.F.R. § 411.355(h) and the exception for EPO and other dialysis-related drugs at 42 C.F.R. § 411.355(g)—are identified by reference to the Code List. The Code List included the annual updates to the codes eligible for the preventive screening tests, immunizations and vaccines exception. However, as in previous years, the Code List does not include any codes eligible for the EPO and other dialysis-related drugs exception (for reasons explained by CMS in the rule). The PFS rule includes tables showing the additions and deletions to the Code List. We expect that, as per usual, the complete list will be posted before the end of the year to the CMS Stark website dedicated to the Code List, found [here](#).

We also expect that the CPI-U Updates page of the CMS Stark website, found [here](#), will be updated before the end of the year to reflect the new compensation limits for the nonmonetary compensation exception (at 42 C.F.R. § 411.357(k)) and medical staff incidental benefits exception (at 42 C.F.R. § 411.357(m)), which are both updated annually for inflation.