

CMS SEEKS INPUT ON STARK LAW CHANGES TO ACCELERATE THE SHIFT TO VALUE-BASED CARE

On June 20, 2018, the Centers for Medicare & Medicaid Services ("CMS") issued a Request for Information ("RFI") seeking feedback from health care industry stakeholders on the burdens of compliance with the Stark Law as it exists today. Earlier in the day, Kelly Cleary from the HHS Office of the General Counsel and HHS Deputy Secretary Eric Hargan previewed the issuance of the RFI in an American Health Lawyers Association webinar and discussed CMS's broader regulatory reform initiative aimed at eliminating barriers to coordinated care delivery.

As background, the Stark Law requires that financial arrangements between health care organizations and referring physicians be structured to fit within Stark's technical regulatory exceptions. In recent rulemakings, industry stakeholders have commented to CMS that the Stark Law is stifling innovation and that changes are necessary to drive needed clinical and financial integration, health care delivery and payment reform. In response, CMS has acknowledged repeatedly that the Stark Law may act as a barrier to coordinated care (CMS's self-proclaimed "top priority") and incentives that lead to improvements in outcomes and reductions in cost. This week's issuance of the RFI and the accompanying webinar remarks indicate that CMS might finally be poised to overhaul the Stark Law to accelerate the shift in the industry to value-based care.

CMS notes in the RFI that it is particularly interested in issues that include, but are not limited to, the structure of financial arrangements between parties that participate in alternative payment models ("APMs") or other novel financial arrangements, the need for revisions or additions to certain exceptions to the Stark Law and terminology related to APMs and the Stark Law (of note is that several years ago CMS proposed, but never finalized, a "value-based" exception intended to cover incentive payments and shared savings).

The RFI provides 20 open-ended discussion questions for stakeholders to provide comment. Questions include, but are not limited to, the following:

- What, if any, additional exceptions to the Stark Law are necessary to protect financial arrangements between entities and referring physicians who participate in APMs (e.g., accountable care organization, bundled payment, two-sided risk and other payment models)?
- What, if any, additional exceptions to the Stark Law are necessary to protect financial arrangements that involve integrating and coordinating care outside of an APM?
- How should CMS define "commercial reasonableness" in the context of the Stark Law?
- Should CMS modify the definition of "fair market value" consistent with the statute and in the context of the Stark Law exceptions?
- When should compensation be considered to "take into account the volume or value of referrals" by a physician or "take into account business generated" between parties to conventional financial arrangements and in the context of APMs and other novel financial arrangements? CMS is requesting examples of compensation formulas that do not "take into account" the volume or value of referrals or other business generated.
- Do barriers exist to qualifying as a "group practice" under the Stark Law?
- Do the following exceptions currently have application and utility, and do they could cover a broader array of arrangements:
 - The special rule for compensation under a physician incentive plan within the exception at 42 CFR 411.357(d) for personal services arrangements;
 - The current exception at 42 CFR 411.357(n) for risk-sharing arrangements; and
 - The current exception at 42 CFR 411.357(g) for remuneration unrelated to designated health services.
- Which provisions, definitions and/or exceptions require additional clarification?

- Could transparency about financial relationships, price transparency or the availability of other data necessary for informed consumer purchasing reduce or eliminate the harms to the Medicare program and its beneficiaries that the Stark Law is intended to address?
- What are the compliance costs for regulated entities?

PRACTICAL TAKEAWAY

These questions shed some light on the areas where CMS may be focusing its reform efforts. Because any enhancements to the Stark Law could have far-reaching implications across the health care industry, we encourage all stakeholders to respond to the RFI to ensure that their input is considered as CMS evaluates potential changes. To be assured consideration, any comments to the RFI must be received by CMS no later than 5 PM on **August 24, 2018**. The full text of the RFI can be downloaded from the Federal Register by clicking [here](#).

If you have any questions or would like additional information or assistance with submitting comments to CMS, please contact:

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