

# PUBLICATION

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## CMS Signals Willingness to Revamp Stark for Coordinated Care Efforts

June 22, 2018

CMS issued a Request for Information (RFI), seeking input from the public on how best to address and mitigate any "undue regulatory impact and burden" of the physician self-referral law ("Stark Law"). The RFI, filed on June 20, 2018, signals a willingness on the part of CMS to consider revisions of the Stark Law to accommodate new payment models. While the RFI is largely focused on the intersection of the Stark Law and care coordination models, it also seeks public input on potential changes to core tenants of the Stark Law – e.g., regarding the definition of "commercial reasonableness" and when compensation should be considered to "take into account other business generated" between parties to an arrangement.

Highlights of those areas CMS is requesting public input include:

- To what extent the Stark Law currently impacts commercial alternative payment models, and to what extent additional Stark Law exceptions may be necessary to protect such arrangements;
- The current utility of the risk-sharing arrangement Stark Law exception;
- To what extent it may be prudent for CMS to add a "special rule for compensation under a physician incentive plan" within the current Stark Law personal services arrangements exception;
- Possible approaches to defining "commercial reasonableness" and "fair market value";
- When compensation should be considered to "take into account the volume or value of referrals" by a physician or "take into account other business generated" between parties to an arrangement (both inside and outside the context of alternative payment models);
- What barriers exist to qualifying as a "group practice" under the Stark Law;
- How CMS could interpret the exception for remuneration unrelated to designated health services (DHS) to cover a broader array of arrangements; and
- The role of transparency in the context of the Stark Law, (e.g., how transparency about a physician's financial relationship may reduce or eliminate harms to the Medicare program and its beneficiaries that the Stark Law is intended to address).

While this is certainly not the first time CMS has requested public input on potential revamps to the Stark Law, this RFI may nonetheless signal increasing momentum for Stark Law reform within the government. As detailed in the RFI, HHS has acknowledged that there are regulatory hurdles to care coordination and addressing these issues is a priority. The Deputy Secretary of HHS, Eric Hargan, launched a "Regulatory Sprint to Coordinated Care" that will identify barriers to coordinated care presented by existing regulatory requirements or prohibitions and considering whether the provisions are unnecessary obstacles to coordinated care. CMS is engaged actively in these efforts and has noted from internal discussions as well as input from external stakeholders that some aspects of the Stark Law may present barriers to coordinated care. The responses to this RFI will inform CMS's analysis of this issue and any response they issue.

As CMS continues to shift payment from fee-for-service to a system that promotes care coordination and quality care to beneficiaries, the development of integrated delivery care models and alternative payment models continues. With this expansion, challenges are created related to the application of the Stark Law to the financial relationships that result from these innovative programs. To date, CMS has issued targeted waivers of the Stark Law to qualifying participants in these programs. However, the waivers only apply to the

specified program and are of no utility to others working towards the same goals but who do not qualify for the waiver. Even for those who are eventually issued an applicable waiver, they encounter challenges while the program is under development prior to the issuance of the waiver. Opportunities and efficiencies are lost in many cases due to the uncertainty of if and when a certain waiver may be provided by CMS. This RFI presents an opportunity to detail the issues faced in the interim periods of alternative payment model development as well as the challenges of those who do not receive a specific waiver of the Stark Law requirements.

In addition to the focus on changes to the Stark Law that would impact efforts being made toward high quality coordinated care in alternative payment programs, CMS has also requested much broader and more general requests related to the application of the Stark Law, some of which touch on areas the industry continues to grapple with in application of the law. CMS even included a request to identify any provisions, definitions, and/or exceptions in the regulations for which additional clarification would be useful. Any rulemaking that results from this RFI could be wide-reaching and impact the application of the Stark Law to new and existing arrangements.

### **Implications for Stakeholders**

This RFI presents an opportunity to voice the challenges faced in implementing coordinated care efforts while complying with the strict liability of the Stark Law and the existing exceptions available. The current Stark Law exceptions were drafted in a fee-for-service world and do not address many of the new financial relationships that could be formed between physicians and DHS entities in bundled payment programs. These efforts are needed to engage the physicians in support of developing ideas focused on promoting high quality care and increased value.

CMS has requested broad comments on many components of the Stark law in previous publications and the Agency does not always issue rulemaking in response to the comments received. However, it is important that the industry take this opportunity to highlight to CMS the challenges being faced, recommendations that have been developed, data that has been collected, and requests for clarification to support forward progress in achieving success in the value based environment that the government continues to promote.

The RFI is scheduled to be published in the Federal Register on June 25, 2018 and comments are due by 5:00 p.m. on Friday, August 24, 2018.