

Dear Administrator Verma:

On behalf of the Association of Freestanding Radiation Oncology Centers (AFROC), we are pleased to have the opportunity to comment on the CMS Request for Information (RFI) soliciting recommendations on Stark Law regulatory modifications that may help facilitate the transition to value based care. We applaud CMS for addressing this important issue and believe that removing Stark Law and related regulatory obstacles has the potential to significantly impact physicians' willingness to enter into arrangements that will bring increased value to the Medicare program and beneficiaries.

AFROC is an association representing non-hospital (freestanding) radiation oncology centers that are owned and operated as part of physician practices. We are extremely concerned that the recent movement toward hospital acquisition of physician practices has the potential to threaten the ongoing viability of non-hospital facilities dedicated to the provision of high quality cancer care. Cancer care is by its nature a multidisciplinary endeavor that requires close cooperation among physicians in numerous specialty areas—including but not limited to urologists and other surgeons, medical and radiation oncologists, diagnostic radiologists, pathologists, pain specialists and others. Integration of these various specialties requires not only clinical cooperation but complex financial arrangements that do not fit neatly into the practice model envisioned by the Stark law, which includes many cancer related services within the scope of "designated health services" ("DHS) e.g. radiation oncology, administration of drugs (medical oncology), pathology, and diagnostic radiology).

In response to the questions set forth in the RFI and in order to better align Stark law restrictions with the objectives of value-based care, we suggest the following changes.

1. Please tell us about either existing or potential arrangements that involve DHS entities and referring physicians that participate in alternative payment models or other novel financial arrangements, whether or not such models and financial arrangements are sponsored by CMS, and identify concerns regarding the applicability of existing exceptions to the physician self-referral law and/or the ability of the arrangements to satisfy the requirements of an existing exception.

AFROC is aware of episode based payment arrangements for radiation oncology services between non-Medicare payers and physician group practices that rely on the in-office ancillary services exception. Under these types of arrangements, a single payment is made based primarily on what type of cancer is being treated and whether the treatment is curative or palliative. Quality measures may be imposed to ensure that care is provided in accordance with clinically accepted standards and protocols.

However, it does not appear to us that the compensation-related provisions of the group practice definition in the Stark law neatly accommodate bonuses based on a group practice member's compliance with these quality standards or based on efficiency measures. In particular, it does not appear that such

incentive payments would qualify as productivity bonuses (which must be based on personal performance).

*Recommendation:* As discussed below, we request that CMS clarify that a group practice's distribution of compensation based on quality or cost based criteria does not constitute compensation that is based on the "volume or value of referrals" as that term is used in the Stark Law.

2. The RFI requests feedback regarding a number of exceptions that preclude referrals from taking into account the volume or value of referrals (e.g. Question 5 (physician incentive plan provisions of personal services exception; Question 11 (definition of what constitutes taking into account referrals).

*Recommendation:* We urge CMS to clarify that a group practice's compensation of a physician member or independent contractor based on that physician's MIPS composite score (or performance measures imposed by non-Medicare payers) or in accordance with clinically supportable utilization guidelines is not deemed to take into account the volume or value of referrals. Performance measures often (and increasingly) require a group to manage physician referral patterns and use of ancillary services), and performance based on such measures is intrinsically different from the type of personal productivity envisioned by the Stark Law regulations. We believe that compensating a physician based on MACRA and other population based measures (including clinically appropriate standards impacting utilization of DHS should be explicitly protected under the Stark Law exceptions. Excluding these types of arrangements from being considered to "take into account volume or value of referrals" would be an appropriate way to accomplish this objective.

3. Question 3 of the RFI requests feedback on what, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physicians who participate in the same alternative payment model.

*Recommendation:* We urge CMS to create a single, comprehensive waiver of the Stark law prohibitions for physicians and entities that participate in Advanced APMs approved by the agency for MACRA purposes and for those non-Medicare arrangements that meet the requirements to qualify as "Other Payer" APMs for MACRA purposes. Such waivers should protect distributions of shared savings and remuneration for "pre-participation" expenses. In light of the priority that CMS has placed on achieving interoperability, we believe that any remuneration necessary to enable APM participants to achieve interoperability standards be expressly exempted from Stark Law prohibitions.

4. Finally, we recognize that CMS' authority to waive application of the Stark Law is not unlimited, and that the agency has no authority to change the underlying statutory prohibition. However, we urge CMS to support the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for making those changes to the Stark law that currently cannot be achieved through regulation, and to encourage Congress to enact legislation that would substantially limit the scope of the compensation-related provisions of the law, which present the greatest obstacles to integrated care.

If you have any questions regarding these comments, please do not hesitate to contact AFROC's Washington counsel, Diane Millman at [dmillman@PowersLaw.com](mailto:dmillman@PowersLaw.com).