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Kim Brandt
Chief Oversight Counsel
United States Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

RE: Congressional Roundtable on Stark Issues Follow-Up

Dear Kim:

Please allow this letter to serve as a follow-up to the Congressional Roundtable on Stark Issues ("Roundtable") held on December 10, 2015. You have requested written comments on the Roundtable topics, specifically the line between technical and more serious violations as well as substantive changes and potential improvements to the Stark Law in light of value-based payment programs. Below please find my thoughts on these matters, and we appreciate the opportunity to comment.

Technical Violations

You have requested information on where to draw the line between "technical violations" and more serious or problematic Stark Law violations. A clear way to distinguish "technical violations" from more problematic Stark Law violations is that a technical violation does not impact the substantive nature of the arrangement and does not pose harm to Federal health care programs or their beneficiaries. For example, if an arrangement otherwise complies with all elements of a particular Stark Law exception but it is missing one or more signatures, is not in writing, and/or the arrangement expired but the services continued without the execution of an amendment or new arrangement (except as otherwise permitted by the indefinite holdover regulations promulgated by CMS), the aforementioned violations would be technical in nature.

Nothing about a missing or late signature, expired arrangement, or a bona fide verbal arrangement (so long as all substantive terms of the arrangement and compensation can be substantiated) should cause harm to Federal health care programs or pose any risk of taking into account the volume or value of referrals or other business generated between the parties.

Distinguishing between technical violations and more substantive Stark Law compliance issues gives CMS the opportunity and resources to focus on behavior that was intended to be prohibited by the Stark Law. By receiving voluminous self-disclosures through the Stark Law Self-Referral Disclosure Protocol ("SRDP") protocol, CMS resources are being tied up for technical issues that pose no threat to Federal health care programs. Our firm has represented

dozens of clients that are facing potential monetary exposure into the millions of dollars as a result of these technical issues, such as missing or late signatures on documents. This potential settlement figure can be crippling for a hospital, particularly smaller hospitals in more rural areas. While the SRDP certainly has its place in the Stark Law compliance arena, creating an alternative method to resolving technical violations would alleviate a portion of CMS's administrative burden as well as avoid the disproportionate penalties health care providers face for non-substantive Stark Law violations.

To address these issues, I recommend that the "Stark Administrative Simplification Act of 2015" (H.R. 776) be revised to reflect changes made in the CY 2016 Physician Fee Schedule Final Rule, like indefinite holdovers for certain exceptions, and moved forward in the legislative process or incorporated into any comprehensive Stark Law reform legislation. This bill creates alternative flat-fee sanctions for technical violations of the Stark Law and an expedited process for their resolution by CMS. The measure would give providers more predictability and certainty regarding the outcome of a technical violation disclosure and free CMS resources to pursue more egregious violations of the Stark Law.

Risk-Sharing Arrangement Exception

As was discussed at the Roundtable, the Stark Law and its exceptions are no longer contemporary with value-based reimbursement. While Medicare reimbursement continues to shift to a focus on quality and efficiency instead of the traditional fee-for-service model, the regulatory environment does not align with the prospect of healthcare providers implementing programs that focus on quality, efficiency, and patient satisfaction. In addition, by allowing certain risk-sharing models, hospitals would have an increased ability to attain the level of physician "buy-in" that is necessary for quality care metric and value-based purchasing success.

In July 2015, in the CY 2016 Physician Fee Schedule Proposed Rule, the Centers for Medicare and Medicaid Services ("CMS") solicited comments on whether the risk-sharing exception should be expanded to protect compensation paid to physicians for certain alternative care delivery models, and if so, what conditions should be imposed to protect Federal health care programs and beneficiaries from abuse.

With regard to possible changes to the Stark Law in light of the various value-based reimbursement programs and initiatives, I recommend the Risk-Sharing Arrangement Exception in the Stark regulations (42 C.F.R. § 411.357(n)) be codified into law and expanded in order to permit risk-sharing arrangements that are both related and unrelated to enrollees of a health plan. In addition, I recommend that these provisions be specifically referenced in the Employment and Personal Services Exceptions so that health care providers have certainty with respect to their more typical physician arrangements.

The rationale for expanding the Risk-Sharing Arrangement Exception to situations with non-enrollees of a health plan is to allow for gainsharing arrangements pursuant to certain cost savings created by providers. Focusing only on health plan enrollees misses the broader picture of changing care delivery processes as a whole, and Federal health care beneficiaries are not singled out in this process. Expanding the current Risk-Sharing Arrangement Exception to

include these types of "gainsharing" payments would benefit providers, patients, and Federal health care programs in the aggregate by reducing administrative burdens and decreasing health care costs. The Civil Monetary Penalty Statute prohibitions on withholding medically necessary services already serves as a proper safeguard for patients.

Related to the Risk-Sharing Arrangements Exception is the Personal Services Arrangements – Physician Incentive Plan Exception (42 U.S.C. 1395nn(e)(3); 42 C.F.R. § 411.357(d)(2)). Again, this exception currently exempts compensation only for services provided to "enrollees." Both of these exceptions should be broadened in order to allow for greater flexibility in the changing health care landscape and the reduction of certain administrative burdens.

Commercial Reasonableness

In order to more fully implement contemporary physician arrangements that do not compromise Federal health care program integrity, I recommend that a definition of "commercial reasonableness" be established. Recent case law has made several assertions that allude to a conclusion that a physician's compensation exceeding the physician's collections cannot be commercially reasonable unless ancillary referrals are considered. Because many hospitals and health care providers operate as not-for-profit, charitable organizations, and because promulgated reimbursement methodologies are beyond the control of health care providers and physicians, the Stark Law needs to address this term.

Commercial reasonableness should be defined to be a legitimate business purpose of the healthcare organization, such as community need, access to care, or fulfillment of call coverage. These types of rationale are similar to IRS Revenue Ruling 97-21, which outlined appropriate scenarios for physician recruitment. In Rev. Rul. 97-21, the IRS was careful to exclude rationale that included violations of the Anti-Kickback Statute, which is appropriate. But the fulfillment of needed services for a health care organization and its community should suffice.

Several hospital service lines are fairly illustrative for operating at a loss (e.g., psychiatric and burn units), and with changes in reimbursement, more service lines will operate at a loss in the future. Unless these issues are addressed, health care providers may be prohibited from providing these services to their communities as a result of a fear of violating the commercial reasonableness standard. In order to preserve necessary services in communities, it is crucial that a workable definition of commercial reasonableness be established.

On a related note, the definition of fair market value and the concept of "takes into account" language found in many of the compensation exceptions should take into consideration changes made to the Risk-Sharing Arrangements Exception as described above. I would caution about creating a "safe harbor" for the definition of fair market value as this was done before with much confusion and little success. A fixed payment and/or a payment methodology that does not change based on increased referrals should satisfy both of these requirements.

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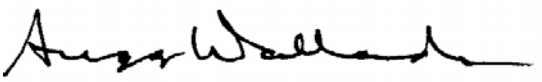
Thank you for the opportunity to submit these comments for your review and consideration. I am happy to meet and discuss further at your convenience, and I welcome another session of the Roundable in the future. Best regards.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, P.C.



Gregg M. Wallander

cc: John Williams, Esq.