February 3, 2016

Kim Brandt
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Tegan Gelfand
House Committee on Ways and Means
1102 Longworth HOB
Washington D.C. 20515

Re: Potential Improvements to the Stark Law

Dear Ms. Brandt and Ms. Gelfand:

On behalf of the American Urological Association (“AUA”), representing nearly 15,000 practicing urologists in the United States and our 8 regional sections, we are writing to comment on potential improvements to the Physician Self-Referral Law (“Stark Law”). We ask that you consider the below comments as you move forward in deliberating revisions to the Stark law.

1. **MACRA and Alternative Payment Models: Stark Law Change is Needed**

Under the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), eligible physicians may earn incentive payments by virtue of their participation in statutorily defined “Alternative Payment Models” (“APMs”), among which include:

- Innovative payment models expanded under the Center for Medicare & Medicaid Innovation (“CMMI”), including Comprehensive Primary Care (“CPC”) initiative participants but not Health Care Innovation Award recipients;
- A Medicare Shared Savings Program accountable care organization (“ACO”); and
- Medicare Health Care Quality Demonstration Program or Medicare Acute Care Episode Demonstration Program; or
- Another demonstration program required by federal law.

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1 42 U.S.C. 1395nn.
While regulations regarding MACRA APMs have yet to be promulgated by CMS, the above regulations make clear that not only it is a CMS priority to incentivize and encourage physician participation in APMs, but that CMS intends to continue to unveil new CMS payment model initiatives, similar to the shared savings and bundled payment models released by CMS to date.

While physicians participating in MACRA APMs may receive incentive payments directly from CMS, without the need for any waiver of the Stark law, the Stark law regime must be modernized to encourage and facilitate physician participation in the above stated MACRA APMs in the first instance.

The current CMS and OIG approach has been piecemeal, to date. With each new APM unveiled by CMS, the OIG will concurrently release fraud and abuse waivers, among which include a waiver of the Stark law provided certain programmatic safeguards are met. It is the AUA’s belief that this approach is fragmented, and leads to significant uncertainty in the wider provider community leading up to CMS’ release of such waivers. A long term Stark solution is required.

To that end, AUA believes that the most direct solution for Congress is to create a legislative Alternative Payment Model Exception. Such an exception would be applicable to all MACRA APM financial arrangements (the “APM Exception”). Enacting this legislation will incentivize meaningful physician participation and engagement in MACRA APMs in furtherance of the government’s cost reduction and quality improvement goals.

An APM Exception should expressly allow for compensation arrangements that take into account the volume or value of referrals, and it would not impose a fair market value requirement. In the alternative, Congress could create legislation creating a new “special compensation rule” related to MACRA APM financial arrangements. We would submit that the new rule, should automatically deem MACRA APM financial arrangements to (1) not take into account the volume or value of referrals” or “other business generated between the parties” and (2) constitute fair market, provided all MACRA APM programmatic requirements were otherwise met. Either legislative solution could contain individualized safeguards similar to those developed by CMS under its shared savings or bundled payment programs.

AUA submits that legislative changes are essential in order to engage physicians. To incentivize meaningful change in care redesign processes and encourage providers to take financial risk, financial incentivizes must not only be offered, but also be proportionally linked, to the amount of work undertaken by a physician. Without such incentivizes tied, at least indirectly, to the volume or value of a physicians’ work, CMS and other APM participants will be left with little leverage in engaging and directing physician efforts.
2. **Drawing the Line: “Technical Violations” and the Stark Law**

   **A. Considering the Stark law history, define Stark law “technical violations” as compensation arrangements that do not otherwise violate the Anti-Kickback statute**

Prior to the Stark Law’s enactment, the government’s ability to regulate inappropriate physician self-referrals was constrained. Specifically, the Anti-Kickback statute was not a vehicle to that could be used to effectively regulate potentially inappropriate physician referrals arising from physician *ownership* interests.

When the Stark law was enacted it covered much more than ownership – it also covered compensation arrangements that could have been handled under the Anti-Kickback statute. Additionally, since the Stark law’s passage, the government’s civil enforcement powers under the Anti-Kickback have increased dramatically – a development, the AUA contends that has only served to further reduce the significance and relevance of the Stark law. For example, any Medicare or Medicaid claim that includes items or services resulting from a violation of the Anti-Kickback statute now constitutes a “false or fraudulent claim” for purposes of the FCA. ² In addition, violators of the Anti-Kickback statute now face substantial financial penalties under the civil monetary penalties (“CMP”) statute, up to $50,000 for each improper act and damages of up to three times the amount of remuneration at issue.³

As such, the AUA believes that the necessity for the strict liability Stark law statute has lessened. While continuing to acknowledge the role the Stark law plays with respect to regulating physician ownership interests, the AUA believes that the Stark law has otherwise served to only unduly burden physicians and physician group practices, and to duplicate enforcement efforts under the Anti-Kickback statute.

Technical violations of the Stark law, including such non-compliant situations as unsigned agreements that are otherwise valid contracts; as currently drafted however, providers are unduly penalized for these minor violations of the law that pose no meaningful threat to patients or federal health care program dollars.

Thus, the AUA urges Congress to consider deeming any Stark law violation with respect to a physician *compensation* arrangement that does not otherwise violate the Anti-Kickback statute, a “technical violation” of the Stark law that would not carry any penalties. Violations of the Stark law with respect to physician ownership interests could continue to be considered problematic and potentially abusive.

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² 42 U.S.C. §1320a-7b (g).
³ 42 U.S.C. § 1320a-7a(a).
B. In the alternative, define Stark law non-compliance as “technical” when the financial arrangement does not confer a financial benefit to the referring physician

In the alternative to AUA’s above proposal, Congress may wish to consider categorizing Stark law violations as “technical,” where a Stark non-compliant arrangement has not resulted in a financial benefit to the referring physician. Stated another way, a Stark violation would only be viewed as problematic, or potentially abusive, if it resulted in a financial benefit to the referring physician; all other violations would be labeled “technical” in nature. The AUA urges Congress to expressly provide that such “technical” violations of the Stark law do not warrant penalties or fines.

An example of this proposal is provided below:

- **Technical violation:** A hospital enters into a medical director agreement with a physician. Several years later the hospital discovers that the arrangement, while otherwise compliant with the Stark law personal service arrangements exception, is unsigned by the physician. Because the lack of signature affords no financial benefit to the physician, this violation of the Stark law would be deemed “technical” in nature.

- **Problematic or potentially abusive violation:** A hospital and physician enter into a medical director agreement. The hospital pays the physician at a rate that is five times the fair market value for the services provided. Here, the physician has been paid an amount that would confer a financial benefit to the physician. This situation could be distinguished from a technical violation of the Stark law.

The AUA believes that the above bright line standard addresses the initial concerns of Congress, as expressed when passing the initial Stark law – the potential for overutilization based on financial interests, inappropriate use of federal health care program dollars, and concerns regarding how financial interests may impact a physician’s medical judgment. The AUA also believes that the above test will lessen, to at least some degree, provider concerns that they will face enormous, disproportionate penalties for mere technical violations of the Stark law that pose no threat to the federal health care program dollars or patients.

3. Stark Law Challenges: General Points for Consideration

AUA commends Congress’ consideration of potential improvements to Stark. As not only CMS, but also the private sector, is increasingly looking to innovate and test new health care delivery and reimbursement models, AUA believes such consideration is warranted. In such a rapidly changing, dynamic environment, the physician community’s focus should not be on mere technical violations of the Stark law, but on modernizing the law.

1. **The cost of compliance**

The Stark law, as currently drafted, has taken a toll on the provider community. Indeed, ensuring compliance with the Stark law for such mundane requirements as ensuring all documents are
signed, when such contracts would otherwise be binding under state law, can ultimately cost physicians and physician practice groups upwards of hundreds of thousands of dollars. Legal counsel and/or consultants must be hired to conduct audits, complete investigations, and draft voluntary self-disclosures. Such cost is compounded by the cost of any payment to the government resulting from a voluntary disclosure. Additionally, uncertainty within the provider community in the face of divergent views of the Stark law across government agencies and the increasing number of *qui tam* whistleblower laws suits creates further compliance costs.

2. *In office ancillaries*

While the AUA promotes the modernization of the Stark law, it urges Congress to be mindful of patient care in doing so. To that end, the AUA does not believe a wholesale change of the Stark law is required. Indeed, the AUA believes certain elements of the Stark law do in fact benefit patient care, specifically, the current list of ancillary services for purposes of the in-office ancillary services exception.

In establishing the in-office ancillary services exception, Congress’ main objective was to “permit the provision of in-office ancillary services for the convenience of patients during their patient visits.” Without the current in-office ancillary services exception and list of in-office ancillary services, patients would be required to schedule follow-up tests and treatments with a second medical provider. Were this to occur, AUA submits that compliance with follow-up tests or treatment would fall off dramatically, harming care coordination efforts.

Thus, because in-office ancillary services, as currently conceived by Congress and implemented by CMS, benefit patients in terms of coordinating care, convenience, and efficiency, AUA believes that the current list of “in-office ancillaries” should not be changed.

3. *Proposed CMS Advisory Opinion Process*

AUA submits that Congress should consider revising the CMS advisory opinion process, similar to that of the existing OIG Advisory Opinion process to allow CMS to permit financial arrangements that may otherwise violate the Stark law, but which would not cause more than a minimal risk of fraud or abuse to Federal Health Care Programs and their beneficiaries. That is, based upon questions and factual representations submitted by a “requester” within the provider community, CMS would opine on factual circumstances in which the government believes constitute technical violations of the Stark law, but that the government would decline to prosecute.

However, and in contrast to the OIG Advisory Opinion process, the AUA believes that CMS advisory opinions regarding what may constitutes a Stark law technical violation should apply to not only the requester of the opinion, but to the entire provider community regulated by the Stark

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4 66 Fed. Reg. 856, 888 (Jan. 4, 2001)
law. This will provide for additional certainty within the provider community and ensure CMS is not inundated with duplicative requests.

Sincerely,

[Signature]

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