February 5, 2016

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

Tegan Gelfand
Professional Staff Member
House Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

**Re:  Invitation to Submit Comments on Stark Law Challenges and Potential Changes**

Dear Ms. Brandt and Ms. Gelfand:

The National Association of ACOs (NAACOS) is the largest organization of Medicare Shared Savings Program (MSSP) ACOs representing approximately 150 MSSP, Next Generation and Pioneer ACOs.  NAACOS is a member-led and member-owned non-profit organization that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health and outcomes, and health care cost efficiency.  NAACOS is pleased to submit the following comments to the Senate Finance and House Ways and Means Committees regarding necessary Stark Law changes that would enable and promote implementation of ACOs and shared savings programs, including the MSSP.

The MSSP fraud and abuse waivers permitted by CMS and the HHS Office of Inspector General (OIG) are fairly broad have allowed for ACOs to form and operate.  However, it may be beneficial to the program and current and future ACOs to create some legislative certainty, as regulations (and the Administrations that promulgate them) can change.  We support adding statutory exceptions to the Stark law related directly to ACOs.  NAACOS also supports uniformity between and among the various ACO programs so that all Medicare providers can play by the same rules.

For brief background relevant to our recommendations, the Stark Law exceptions cover financial relationships.  For example, where a physician and hospital have a direct compensation arrangement – in the form of a medical director agreement perhaps – the physician may not refer Medicare fee-for-service beneficiaries to the hospital for inpatient or outpatient services, and the hospital may not bill for any such services furnished to such beneficiaries, unless the arrangement between the parties fits into a Stark Law exception, such as the exception for

personal services arrangements, 42 U.S.C. §1395nn(e)(3); 42 C.F.R. §411.357(d), or for arrangements that are consistent with fair market value, 42 C.F.R. §411.357(l).

Other Stark Law exceptions, however, cover services. For example, pursuant to the "pre-paid plans exception," 42 U.S.C. §1395nn(b)(3); 42 C.F.R. §411.355(c), where a physician and hospital have a direct compensation arrangement, the physician may refer Medicare beneficiaries who are enrolled in a Medicare Advantage plan to the hospital for inpatient or outpatient services, and the hospital may bill for any such services furnished to such beneficiaries irrespective of whether the direct compensation arrangement between the parties fits into a Stark Law exception.

In order to address, at least in part, the uncertainty and fragmentation relating to whether and the extent to which ACO arrangements implicate the Stark Law, Congress should consider amending the Stark Law to create two new exceptions:

1.    The first exception would be similar to the prepaid plans exception, and would protect any designated health services (DHS) furnished to a Medicare beneficiary who is assigned to an MSSP, Pioneer, or Next Generation ACO (or any other ACO model established by CMS or tested under the Innovation Center).

2.    The second exception would be similar to the existing exception for risk sharing arrangements, 42 C.F.R. §411.357(n), and would protect any direct or indirect compensation arrangements between a physician and an MSSP, Pioneer, Next Generation ACO, or other CMS or Innovation Center ACO model as long as the arrangement is reasonably related to one of the purposes of the MSSP, Pioneer, or Next Generation ACO program, respectively.

NAACOS appreciates the opportunity to provide recommendations to the committees and we look forward to working with you to improve the MSSP, ACOs, and the federal laws that govern such programs.

Sincerely,

Clifton Gaus
CEO