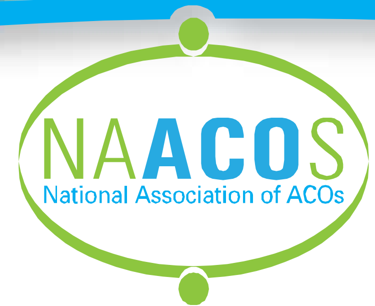

January 25, 2017

Office of Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted via email to: CompetitionRFI@hhs.gov

Re: Request for Information on Promoting Healthcare Choice and Competition Across the United States

Office of Assistant Secretary for Planning and Evaluation (ASPE):

NAACOS is pleased to submit our comments in response to this request for information (RFI) on Promoting Healthcare Choice and Competition Across the United States. NAACOS is the largest association of ACOs, representing more than 4 million beneficiary lives through 300 Medicare Shared Savings Program (MSSP) ACOs, Next Generation, and commercial ACOs. NAACOS is an ACO 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 and its members are committed to transforming the way healthcare is delivered and paid for. Our members are at the forefront of this transformation effort and have invested significant time and resources to their success, which will ultimately improve care for Medicare beneficiaries and reduce costs for CMS.

ACOs provide a voluntary market alternative to consolidation

The Department of Health and Human Services (HHS) notes it is interested in soliciting public comments on the extent to which existing State and Federal laws, regulations, guidance, requirements and policies limit choice and competition across all healthcare markets. ACOs provide opportunities for hospitals and physician practices to better coordinate care of the patients they serve to provide higher quality care and work collaboratively to reduce healthcare costs. The existence of ACOs provide an alternative to hospital mergers and consolidation by allowing physician practices to collaborate with hospitals through the ACO program. This provides an opportunity for clinical integration and organizational integration to allow organizations to provide more coordinated care for patients they serve without consolidation, providing physician practices with increased options in the marketplace. The ACO model removes the financial incentives for consolidation by allowing for clinical, organizational and certain financial integration to better coordinate care for patients ACOs serve. However, there are further steps the Centers for Medicare & Medicaid Services (CMS) and HHS can make to further enhance this collaboration among ACO participants to allow further clinical integration and better coordinated care for patients at lower costs while preventing increased consolidation. We outline these issues in our comments below.

CMS must make changes to the ACO program to support the ACO model and to allow ACOs to compete with the Medicare Advantage

Medicare fee-for-service, ACOs and Medicare Advantage are three main options for Medicare providers and beneficiaries. To prevent the need for consolidation, we urge CMS to support the ACO model by making the changes below to the ACO program. Further, we urge HHS to enhance choice and competition for healthcare providers choosing among numerous Medicare programs. As such, it is critical that CMS provide an even playing field for ACOs to fairly compete with Medicare Advantage to ensure Medicare beneficiaries are served equally well in either of these alternatives to traditional fee-for-service. Currently there are key program differences that put ACOs at a disadvantage, and we urge CMS to make changes to these policies. For example, there are key risk adjustment methodology differences which put ACOs at a distinct disadvantage. Our comments below outline key program changes that would allow ACOs to more fairly compete with Medicare Advantage.

Allow ACOs to increase beneficiary engagement

CMS does not allow ACOs to incentivize beneficiaries to seek treatment from the providers the ACO has identified as most efficient and high quality. Unlike the Medicare Advantage program, ACOs are unable to provide incentives for beneficiary engagement with the ACO's most efficient providers. This in turn creates challenges for the ACO in communicating with beneficiaries regarding their preferred providers for treatment. These are the providers engaged with the ACO and focused on providing coordinated, high quality care. NAACOS urges CMS to work with Congress to afford ACOs the same opportunities that are currently provided to Medicare Advantage plans to increase beneficiary engagement through incentives for beneficiaries choosing high quality, efficient providers that work collaboratively with the ACO.

Make changes to Physician Self-Referral Law

For several years healthcare industry stakeholders and policy makers have discussed the extent to which the federal physician self-referral law (or "Stark Law") prevents or inhibits integrated care models critical to an efficient, effective and successful transition to value-based reimbursement. There is a consensus that the Stark Law inhibits a wide range of integrated care initiatives. To their credit, through the establishment of multiple fraud and abuse waiver programs, CMS and HHS-Office of Inspector General (OIG) have attempted to address at least some of the industry's concerns. While these waivers have been helpful, they are too limited. For example, in order for an ACO to effectively promote accountability for the quality, cost, and overall care for both Medicare and other patient populations, the ACO and its participants must (1) enter into arrangements with outside parties and (2) address more than just Medicare fee-for-service patients.

With respect to the first issue, although the preamble to the waivers suggests that third-party arrangements are permissible, the waiver language itself is ambiguous, providing that MSSP waivers protect arrangements "of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof." 80 Fed. Reg. 66726, 66735-36 (preamble) and 66743 (participation waiver) (Oct. 29, 2015). Regarding the second issue, while the existing fraud and abuse waivers may protect shared savings arrangements with providers as they relate to the specific federal program at issue (e.g., the MSSP), it is less clear that they protect such arrangements as they relate to other patient categories (e.g., commercially insured patients). As a result, there is significant uncertainty concerning whether or the extent to which an incentive program offered to a physician with respect to his or her assigned MSSP patients may, without creating potential Stark Law issues, also be offered to the same physician for his non-MSSP patients. This uncertainty inhibits the implementation of efficient, broad-based, clinically-supported incentive programs that might otherwise serve to promote accountability for the quality, cost, and overall care for both Medicare and other patient populations. We urge CMS and HHS to provide increased Stark Law protection for ACOs, especially as it pertains to addressing the uncertainty about acceptable arrangements with parties outside of the ACO and for patients beyond traditional Medicare.

Reduce quality burdens for ACOs
ACOs are currently evaluated on 31 quality measures, while other programs use significantly fewer measures such as the Merit-Based Incentive Payment System (MIPS), which requires clinicians to report on only six quality measures. Most of the ACO measures are reported through the Web Interface. ACOs receive this reporting tool in the first quarter following the performance year and must collect the necessary data and report on patients specified by CMS. Other ACO measures are calculated using administrative claims data and require no reporting to CMS; however, ACOs must still put in place operational processes necessary to track their performance on these measures. Therefore, the total burden for reporting quality measures is significant and we urge CMS to find ways to reduce this burden to allow ACOs to more fairly compete with Medicare Advantage.

ACOs are already held to high standards in improving care for the patients they serve, and they are evaluated on and responsible for a patient's total cost of care. Therefore, quality improvement is inherent to the ACO model and an ACO's key activities to be successful in the program. For this reason, requiring evaluation on 31 quality measures is unnecessary and adds a significant burden on ACOs. NAACOS urges CMS to reduce the number of ACO quality measures and to place a focus on outcomes measures over process measures. Paring down the number of measures ACOs are evaluated on would reduce the burden on ACOs and therefore allow the organizations to focus on the process improvement and quality improvement activities they find most impactful.

Improve program transparency
ACOs rely on CMS and its contractors to execute complex program methodologies and operations, such as determining risk adjustment data and beneficiary assignment and calculating benchmarks and expenditures. These methodologies and calculations are essential to the ACO program and determine whether an ACO is successful. However, these methodologies and their corresponding calculations are not fully disclosed. While CMS shares its general approaches, and ACOs do their best to replicate CMS's work, the agency does not provide the level of detail needed for ACOs to make their own precise calculations. CMS should be fully transparent with its methodologies and calculations, and ACOs should be able to replicate them on their own. We urge CMS to share the exact algorithms for these important methodologies and calculations. This will help ensure transparency and accountability of CMS. The only way ACOs can be competitive in the market and ultimately successful is with a transparent government partner. It is essential that CMS provide increased transparency of critical ACO program methodologies including, the details ACOs need to replicate formulas and make their own calculations.

Expand use of payment rule waivers across ACO programs
Currently CMS affords certain ACOs relief from a number of cumbersome payment rules that actually prohibit care coordination and can increase costs. We urge CMS to expand the use of these payment rule waivers to extend to all ACOs. This includes the Skilled Nursing Facility (SNF) 3-day Rule. Eliminating the requirement of a 3-day inpatient stay prior to SNF (or swing-bed Critical Access Hospital admission) admittance will allow ACOs to provide the right care for the patient in the most appropriate location. We also request that CMS waive certain telehealth billing restrictions to increase the use of these services by all ACOs. Specifically, elimination of the geographic components of the originating site requirements will allow all ACOs to have the ability to provide needed telehealth services in areas other than those classified as rural areas by CMS (currently defined as a rural Health Professional Shortage Area [HPSA] located either outside of a Metropolitan Statistical Area [MSA] or in a rural census tract). We also request that CMS allow beneficiaries to receive telehealth services from their place of residence.

Additionally, we urge CMS to waive certain post-discharge home visit supervision requirements to allow for broader use of these services by ACOs when clinically appropriate. We ask that CMS allow physicians to contract with licensed clinicians to provide these home visit services using general instead of direct

supervision requirements specified at 42 CFR § 410.32(b)(3). This will provide all ACOs with needed flexibility during the critical post-discharge time period. Finally, we ask CMS to afford all ACOs with the ability to provide waived co-payments for primary care services provided by the ACO's providers to encourage patients' use of these critical services. CMS should afford all ACOs with every opportunity for success in reducing costs for its patients by allowing ACOs to use these high value services, and we request that these waivers apply to all ACO models.

Modify benchmark methodology
The methodology for establishing, updating and rebasing ACO benchmarks is a foundational part of the ACO program. Without accurate and fair benchmarks, ACOs are unlikely to be able to succeed. Modifying the ACO benchmarking methodology will support the overall ACO program, which as explained above will help prevent further consolidation in the healthcare industry. We appreciate CMS's efforts to adjust the process for rebasing ACO benchmarks as detailed in the final rule, *Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations – Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations* (published in the June 10, 2016 Federal Register), which introduces a component of regional expenditure data into rebased benchmarks. However, there are a number of remaining rebased benchmarking issues that were not appropriately addressed by CMS in that rule. Specifically, there are issues related to: (1) the definition of the regional reference population that includes ACO-assigned beneficiaries, a reversal of previous policy resulting in CMS no longer appropriately accounting for savings generated in a previous agreement, and (2) CMS not allowing 2012/2013 MSSP ACOs to move to the new methodology prior to 2019. CMS must make further changes to that methodology to ensure fair and accurate benchmarks. Regarding the definition of the regional reference population, CMS does not include Medicare Advantage beneficiaries in the FFS benchmark used to determine payments to Medicare Advantage plans, and therefore the agency should not do so with ACOs. NAACOS urges CMS to modify MSSP rebased benchmarking policies at CFR 42 §425.603 to remove ACO-assigned beneficiaries from the regional reference population, account for all savings generated in previous agreement periods by adding those savings back to rebased benchmarks, and allow 2012/2013 ACOs to transition to regionally based benchmarks before 2019.

Make changes to risk adjustment methodologies
Risk adjustment is another critical program methodology that necessitates changes to make it fair and accurate. Risk adjustment is used across many CMS programs, including the MSSP and a number of others within traditional Medicare and in Medicare Advantage (MA). While many programs rely on Hierarchical Condition Categories (HCC) risk scores, there are important program variations in how CMS approaches risk adjustment. The inconsistent approach to risk adjustment in Medicare helps and harms various programs depending on the details of the methodology. The MSSP risk adjustment methodology unfairly penalizes ACOs compared to other programs. Specifically, for continuously assigned ACO beneficiaries, CMS considers changes based on demographic data but typically will only *decrease* risk scores for improved health status with very limited opportunity to increase risk scores for patients that become sicker or develop new conditions over time. This is a fundamentally flawed approach since risk scores for continuously assigned beneficiaries can decrease but cannot increase. In contrast, under MA beneficiaries with lower-than-average predicted costs have their payments decreased incrementally based on their risk profile and beneficiaries with higher-than-average predicted costs have their payments increased incrementally based on their risk profile. We urge CMS to address the flawed MSSP risk adjustment methodology for continuously assigned beneficiaries by modifying CFR 42 § 425.602(a)(9) and more broadly allowing risk scores to increase as a result of changes in health status. At a minimum, for the MSSP CMS should apply a similar approach used under the Next Generation ACO Model where CMS will increase the financial target by up to 3 percent if the population's risk status increases.

Provide timely, actionable data to healthcare providers in ACOs
It is widely recognized that giving timely, actionable data to healthcare providers allows them to work closely with beneficiaries to effectively manage chronic conditions or prevent health conditions from worsening. Many ACOs are successful because of their focus on care coordination for chronic conditions, emphasis on providing the right care in the right setting, and preventing avoidable and costly complications or hospital readmissions. However, to effectively manage a beneficiary's health, ACOs need more timely and in-depth data. CMS provides some data, but it is delayed by weeks or months and is therefore not always actionable. In order to make the ACO program competitive with Medicare Advantage, CMS must provide more timely and transparent data. The data available in the HIPAA (Health Insurance Portability and Accountability Act) Eligibility Transaction System (HETS) is very meaningful and should be provided in real time to ACOs for their beneficiaries. This would allow ACO providers to communicate with treating providers at the hospital and to work with the beneficiary upon his or her release to ensure optimal treatment, medication adherence and follow up care. We urge CMS to develop a mechanism to share more robust health data, including that from HETS, with ACOs in real time to enhance care coordination, improve outcomes and reduce costs.

Make Changes to Data Use Agreement requirements
We have repeatedly requested that CMS provide clarification on ACOs' permissible use of data under requirements from DUAs signed by ACOs. There has long been confusion about DUA cell suppression requirements and how DUA requirements affect use of aggregated data from ACO claim and claim line feed (CCLF) files. While we appreciate that CMS has recently made some clarifications in this area, more education and resources from the agency are needed to ensure ACOs and other stakeholders fully understand how the DUA requirements apply to real world situations ACOs face. We request CMS simplify DUA requirements by clearly defining "derivative data" and the correlation between that derivative data and the cell suppression requirements in the DUA and provide more education in this area.

Further, we urge the agency to simplify the process for amending the list of parties covered under an ACO's DUA, to allow ACOs to submit notification of the addition to CMS without having to wait for approval. Currently, to add a party, an ACO must go through a process with CMS to amend its DUA list, which can take anywhere from a few days to a few weeks. We have even seen a few instances of it taking a few months. The time delay and uncertainty impedes an ACO's ability to move forward working with the new vendor or organization, which inhibits an ACO's operations and its ability to execute innovative new approaches to care coordination and other essential ACO activities. In contrast to the arduous and uncertain process required under MSSP, the Next Generation Model and Medicare Advantage do not require such regulatory burdens and there is no similar approval process. Organizations being added to an ACO's DUA must review and sign an agreement to abide by the requirements covered in the DUA. As long as the activities are covered under health care operations and a business associate agreement is in place, an ACO should be able to have them agree with the terms specified in the DUA without necessitating a formal CMS approval. Rather, the ACO could submit notice of the addition to CMS and instead of waiting for approval, the party would be added to the DUA and CMS could contact the ACO if follow up is needed. Therefore, we urge CMS to remove the MSSP approval process to add a new party to an ACO's DUA.

Modify repayment mechanism requirements
To be eligible to participate in a two-sided ACO model (the Next Generation ACO Model or MSSP Tracks 1+, 2 or 3), an ACO must demonstrate that it has established an adequate repayment mechanism. These ACOs must demonstrate that they would be able to repay shared losses incurred at any time within their agreement period and for a time afterwards. CMS accepts funds in escrow, a line of credit, a surety bond, or a combination of those mechanisms as adequate repayment mechanisms. For MSSP, the repayment mechanism must be in effect for the duration of the ACO's three-year agreement period, plus a 24 month "tail period" following the expiration of the three-year agreement, for a total of a five-year term. Securing repayment mechanisms is a regulatory burden, which is time consuming and costly for ACOs. We urge CMS

to remove the requirement for two-sided ACOs to secure repayment mechanisms. If this regulatory burden is not removed, at a minimum, CMS should remove the tail period following the agreement period and should provide new repayment mechanisms, including reinstating reinsurance and introducing an option for a future withhold of Medicare payments as repayment mechanisms. To allow all types of organizations, including physician-led organizations, to participate in the ACO program CMS must make modifications to the repayment mechanism requirements. Affording provider-led organizations the ACO option for participation can prevent the need for ownership changes that could otherwise lead to consolidation.

Simplify marketing requirements
The current marketing requirements ACOs must adhere to are complex and add a significant amount of burden on the ACO's operation. What's more, these government requirements inhibit an ACO's ability to communicate effectively with its patients and community to explain the benefits and services provided by ACOs. CMS must allow ACOs to invest resources in the ways the organization finds most effective. This requirement is unnecessary and therefore a drain on an ACO's precious resources. Therefore, NAACOS urges CMS to simplify ACO marketing requirements by removing the requirement to submit internal provider facing materials to CMS.

Remove EHR certification requirements to reduce burden and increase competition in the vendor marketplace
It is unnecessary for the agency to require use of a specific certified EHR product. The current industry standard allows for a broad range of data collection capabilities; therefore, CMS should allow an ACO or group practice to choose the EHR product that best suits their needs. When CMS requires specific certifications, vendors must constantly change their products to obtain updated certification. These costs are then passed on to the providers and can total in the tens of thousands of dollars for large organizations. What's more, the changes create inefficiencies in practice as clinicians must constantly adapt to and learn new systems as products are upgraded to maintain certification. This can also result in patient safety issues. Also, in many cases vendors are unable to maintain their certification by complying with updated certification criteria and as a result leave practices without a viable option to participate in certain CMS programs like Advancing Clinical Information (ACI). NAACOS urges CMS to instead remove requirements for ACOs to use specific certified EHR products and instead allow ACOs to choose the EHR that is best for their organization.

Conclusion

In closing, we respect HHS's efforts to further improve the healthcare marketplace by ensuring competition and appropriate collaboration among healthcare organizations to better serve patients. We believe the ACO model serves as an example of providing market-driven options for practices and hospitals to collaborate without needing to consolidate. We look forward to working with the Administration on finding ways to further increase competition in the marketplace.

Sincerely,

Allison Brennan
Vice-President of Policy
National Association of ACOs