

July 6, 2018
Mr. Alex Azar
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Request for Information on a Healthcare Sector Innovation and Investment Workgroup

Dear Secretary Azar:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the Request for Information (RFI) on Healthcare Sector Innovation and Investment Workgroup (the Workgroup), released by the U.S. Department of Health and Human Services (HHS) on June 7, 2018. As the largest association of Accountable Care Organizations (ACOs) representing more than 5 million beneficiary lives through more than 300 Medicare Shared Savings Program (MSSP), Next Generation, and commercial ACOs, NAACOS and its members are deeply committed to the transition to value-based care. 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.

In this RFI, HHS describes its intention to provide a forum for HHS leadership to engage in a dialogue with those focused on innovating and investing in the healthcare industry, such as healthcare innovation-focused companies, healthcare startup incubators and accelerators, healthcare investment professionals, healthcare-focused private equity firms, healthcare-focused venture capital firms, and lenders to healthcare investors and innovators. HHS has stated that it envisions the Workgroup as a forum to hear the individual perspectives of attendees and foster new and innovative approaches to tackle the complicated challenges facing the healthcare industry.

Specifically, HHS seeks comments on how to structure the Workgroup in order to best support communication and understanding between these parties that will spur investment in the healthcare industry, increase competition, improve innovation, and allow capital investment in the healthcare sector to have a more significant impact on the health and wellbeing of Americans. NAACOS's views on this effort are detailed below.

Areas of Inquiry

RFI Question 1: Should the Workgroup review recent developments in health innovation and investing?

NAACOS Response: Yes. Consistent with the HHS's Regulatory Sprint to Coordinated Care, and the Agency's strong commitment to reward value over volume, the Workgroup should review recent developments including those in ACO design and delivery, and specifically the opportunities and challenges of the MSSP tracks, Track 1+, and the Next Generation Model. This focus is also appropriate as it will support CMS's ongoing statutory obligations to implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which focuses on Medicare shifting providers into Alternative Payment Models, such as ACOs.

As part of its work evaluating health innovation developments, the Workgroup should examine the growing body of evidence on ACO performance and consider how to strengthen ACO models. For example, according to a CMS presentation on the MSSP 2016 performance year results, which is the most recent performance data available, ACOs subject to pay-for-performance quality measures earned an average quality score of 95 percent in 2016. Further, MSSP ACOs that earned shared savings in 2016 had a significant decline in inpatient hospital expenditures and utilization as well as decreased home health, Skilled Nursing Facility and imaging expenditures. When combining the 2016 MSSP results with Innovation Center ACO programs including the Next Generation Model, the Pioneer ACO Model, and the Comprehensive ESRD Care Model (CEC) the evidence is even stronger. According to CMS's Public Use Files on program performance, collectively in 2016 Medicare ACOs generated \$836 million in gross savings and \$71.4 million in net savings. Innovation Center ACOs all demonstrated very high quality; Pioneer ACOs had an average quality score of 93 percent and Next Generation and CEC model ACOs all had 100 percent in their initial pay-for-reporting years.

As noted by the Medicare Payment Advisory Commission (MedPAC) in their June 2018 report, Chapter 8: Medicare Accountable Care Organization Models: Recent Performance and Long-term Issues, some of the most insightful analysis of ACO savings comes from experts at Harvard University who found that the CMS benchmarks underestimate true savings and that MSSP ACOs have saved Medicare hundreds of millions of dollars. Accurate measurement of ACO savings requires a credible way to estimate what spending would be in the absence of the ACO program. Peer-reviewed studies by Harvard researchers showed that Medicare saved nearly \$290 million net of CMS shared savings in the MSSP through 2014, and research through 2015 is expected to be released soon. Furthermore, these studies show that ACO savings have increased over time as ACOs gain experience in the program. In conclusion, there is growing evidence about the positive effects of Medicare ACO programs, and it is essential that the Workgroup review recent developments and consider ways to further improve these programs.

We also urge the Workgroup to also look outside of the federal health care programs to identify valuebased care models that are working in commercial markets. Commercial ACO arrangements include significant variation and innovation and are demonstrating positive results, all of which would provide valuable lessons for the Workgroup. For example, according to United Healthcare's February 2018 Value-Based Care Report, United notes that their employer-sponsored and individual network ACOs are better on 87 percent of the top quality measures than non-ACOs, and these ACOs have 17 percent fewer hospital admissions than non-ACOs.

RFI Question 2: Should the workgroup examine perceived barriers to innovation and competition in the healthcare industry?

NAACOS Response. Yes. In the context of the MSSP, even though ACOs are afforded waivers from certain federal laws, such as the federal self-referral and anti-kickback statutes, there continue to be barriers to innovation and competition which are problematic for many ACOs. For example, we request 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. There are also barriers in place from misuse of the Health Insurance Portability and Accountability Act (HIPAA), such as refusal by the Centers for Medicare & Medicaid Services to provide ACOs with real-time care coordination data about their assigned beneficiaries. This data is available in the HIPAA Eligibility Transaction System (HETS) and should be provided real-time to ACOs to enable their care coordination efforts. Consistent with the CMS solicitation for information regarding the federal self-referral or "Stark Law," HHS should identify existing regulatory measures which may enable innovation and competition for ACOs.

RFI Question 3: Should the workgroup encourage outside parties to provide HHS with information about how they are affected by HHS programs or regulatory requirements? Specifically, should the workgroup provide a forum for attendees to share their perspectives as to how the Department may improve relevant regulations, guidance, or other documents?

NAACOS Response. Yes, we support additional forums and processes to allow outside parties to provide HHS with information regarding how they are affected by HHS programs or regulatory requirements. We strongly urge HHS, however, to provide an opportunity for public comment when considering such information, and to commit to transparency regarding proposals and regulatory requirements that are undergoing review through the work of the Workgroup. We would not support the Workgroup, for example, circumventing the requirements of the Administrative Procedures Act and sunshine mechanisms whereby interested stakeholders have the opportunity to review and provide input on significant health policy developments.

RFI Question 4: Should the Workgroup examine ways to encourage private sector investment to help combat health crises?

NAACOS Response: Yes. In the area of value-based care design and delivery, we urge HHS to engage with commercial ACOs to better understand what care coordination models are working in commercial markets and how to better utilize those lessons learned to reduce regulatory barriers to participation in the MSSP. There is increasing interest in private sector investment in revolutionizing the nation's health care industry to be more efficient and patient-focused, and there is specific interest in financially backing promising models such as ACOs. The Workgroup should examine existing and future investment opportunities focused on payment and delivery models, such as ACOs, as well as investments focused on specific health crises.

RFI Question 5: What other areas of focus would best help the Department engage with diverse subsectors of the healthcare industry and investment industry in order to increase innovation and investment in the healthcare sector?

NAACOS Response: We strongly urge HHS to include ACOs in the Workgroup's areas of focus. ACOs are arrangements between diverse members of the healthcare community, including physician groups, hospitals, post-acute providers, technology companies, and private investors. ACOs are unique in that they bring together these diverse stakeholders to work collaboratively to design care models that both increase

quality and decrease cost; as such, ACOs can inform HHS as to how various care coordination activities have worked or not worked for various ACO partners and patients.

Workgroup Organization

RFI Question 6: How should the workgroup should be convened and structured, including what subsectors of the healthcare economy should be invited to participate, and the most effective size.

NAACOS Response: We strongly urge HHS to involve NAACOS leadership in the Workgroup; as the leading organization representing ACOs, we have an in-depth understanding of clinical and care delivery innovations taking place across the country as part of ACO arrangements and initiatives. We are also uniquely poised to facilitate the participation of ACO leaders, both on the clinical and operational side, to participate as members of the Workgroup. NAACOS would be pleased to help HHS identify members for the Workgroup who have practical experience with ACO design and development, as well as members who can provide feedback regarding new policy proposals and recommendations.

RFI Question 7: How should the agency structure meetings or other engagements in order to best facilitate the exchange of information and the presentation of attendees' individual perspectives?

NAACOS Response: HHS should provide notice on each meeting publicly and be transparent regarding the Workgroup meeting deliberations, reports, and minutes. HHS may look to the CMS Physician-Focused Payment Model Technical Advisory Committee (PTAC) as an example for the Workgroup; PTAC provides significant and meaningful information regarding the process for idea submission and those concepts and proposals which are under PTAC review.

RFI Question 8: The Department seeks comment on how suitable attendees should be identified and selected to attend and engage in an exchange of ideas about the Department's goals of increasing innovation and investment in the healthcare sector.

NAACOS Response: Similar to other HHS workgroup activities, HHS should provide an opportunity for nomination of members of the Workgroup, and such members should serve for a limited term. Whatever the process for selecting members, we strongly urge HHS to include at least one member who is an expert on ACOs and value-based care design to help the Workgroup with its consideration of issues concerning the movement from volume to value-centered healthcare. Given the prominent role ACOs have played driving the shift from volume- to value-based care and considering the growing number of ACOs and the millions of beneficiaries they cover, ACO involvement in the Workgroup is critical.

<u>Additional Opportunities</u>

RFI Question 9: What are other opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the healthcare industry, including alternatives to the workgroup structure discussed in this request for information?

NAACOS Response: We strongly support HHS's efforts heretofore to promote open lines of communication between the Agency and its constituencies, including NAACOS. We urge HHS to create additional opportunities for increased engagement and dialogue between HHS and healthcare innovators, including ACOs, as new policies are considered and developed.

Conclusion

NAACOS is pleased to provide this feedback on behalf of our members and welcomes the opportunity to continue to engage with HHS on this important effort. Specifically, we request that HHS include value-based health care delivery and accountable care models in the strategic initiatives of the Workgroup. Further, NAACOS readily offer its assistance as a member of the Workgroup and, if desirable, to identify Workgroup participant candidates and facilitating participation, as appropriate. We look forward to our continued engagement as the Workgroup takes shape. If you have any questions regarding our comments herein, please contact me at the email address provided below.

Sincerely,

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National Association of ACOs

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