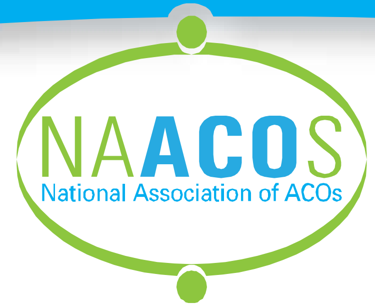

September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: (CMS-1676-P) Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Dear Administrator Verma:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments on the proposed rule *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program,* published in the *Federal Register* on July 21, 2017.

NAACOS is the largest association of ACOs, representing more than 3.7 million beneficiary lives through 250 Medicare Shared Savings Program (MSSP), 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. Our members, more than many other healthcare organizations, want to see an effective, coordinated patient-centric care process. Our recommendations reflect our expectation and desire to see ACOs achieve the long-term sustainability necessary to enhance care coordination and health outcomes for Medicare beneficiaries, reduce healthcare costs, and improve quality in the Medicare program.

Summary of Key Recommendations

As detailed in the comments below, in the final 2018 Medicare Physician Fee Schedule (PFS), we urge the agency to:

- Finalize the proposal to update the primary care codes used in MSSP assignment
- Enhance the role FQHCs/RHCs in MSSP assignment and allow FQHCs/RHCs to bill for a wide range of care management services

- Finalize proposals to alleviate burdens associated with the initial MSSP application and the 3-day SNF waiver application
- Finalize proposed changes to the quality measures validation process while lowering the audit threshold to 70 percent
- Retain its responsibility for establishing and updating RVUs and payment rates under the Medicare PFS and not relinquish that authority to the RUC
- Finalize the use of CPT codes to replace current care management codes and reduce regulatory burdens for care management
- Provide greater transparency around the impact of overlapping programs such as episode payments on ACOs, including the disclosure of all related program costs, both interim and final, as well as a detailed explanation of the impact of these costs on the ACO
- Continue to seek consultation from stakeholders to further refine the proposed patient relationship categories and codes to ensure the codes are ultimately useful and create reliable ways to attribute costs of care to clinicians without adding significant burden on providers
- Hold clinicians accountable in value-based payment programs like PQRS, the Value Modifier and Meaningful Use and reward high-performing clinicians who have invested heavily in performance improvement and should therefore be rewarded for this investment, time, and effort
- Expand the list of covered Medicare telehealth services

Comments on 2018 Medicare PFS Proposals

Medicare Shared Savings Program Proposals

New Primary Care Codes for MSSP Assignment

> **Key comment: NAACOS supports CMS's proposal to update the list of primary care codes used for MSSP assignment**

Proposal*:* MSSP assignment is based on where beneficiaries receive the plurality of their primary care, which is defined by a specific set of billing codes identified and periodically updated by CMS. The agency proposes to modify the list of primary care codes used for MSSP assignment to include new primary care codes that were added to Medicare in recent years. Specifically, beginning in 2018 for performance year 2019 and subsequent years the agency proposes to add the following codes to the list of primary care codes used for MSSP assignment:
• Complex CCM codes 99487 and 99489, CCM add on-code G0506
• Behavioral health integration codes G0502, G0503, G0504, G0507

Comments: NAACOS supports updating the definition of primary care codes used for MSSP assignment. Assignment is a critical program methodology that determines the beneficiary population for which an ACO is held accountable. CMS should continue to refine the primary care codes used in assignment, and we request that the agency do so in a timely manner as codes are finalized for inclusion in the PFS.

Assignment Modifications for ACOs with RHC and FQHC Participants

> **Key comment: NAACOS supports CMS's efforts to better incorporate FQHCs/RHCs into MSSP assignment and simplify the process but cautions the agency to retain its required focus on basing assignment on primary care.**

Proposal: Per the 21st Century Cures Act, CMS proposes to assign beneficiaries to MSSP ACOs based increasingly on their utilization of services furnished by RHCs and FQHCs, effective beginning with the 2019 performance year. Therefore, CMS proposes the following modifications to the MSSP assignment process:

- Remove the requirement that ACOs attest to the physicians who directly provide primary care services in each RHC or FQHC that is an ACO participant and/or provider/supplier in the ACO. Submission of National Provider Identifiers (NPIs) or other identifying information would no longer be necessary.
- Use all RHC and FQHC claims to establish beneficiary eligibility to be assigned to the ACO in the assignment pre-step.
- Include all RHC and FQHC claims in step one of assignment.
- Remove revenue center codes from the definition of primary care services.

CMS proposes to adjust all ACO benchmarks at the start of 2019 so that the ACO benchmarks reflect the use of the same assignment rules as will apply during that performance year.

Comment: We strongly support appropriately including FQHCs and RHCs in the assignment process. Many ACOs with FQHCs/RHCs have had ongoing concerns about not adequately involving these organizations in assignment, and we are pleased to see CMS propose changes to address this. We strongly support CMS removing requirements that ACOs attest to the physicians who provide primary care services in each RHC/FQHC, which is a requirement that is not only onerous but also prohibits additions to that list during a performance year. Removing that requirement eliminates an administrative burden on ACOs and recognizes the work of new providers that join the organization during the performance year.

By removing the attestation requirement, CMS would treat a service reported on an RHC or FQHC institutional claim as a primary care service furnished by a primary care physician. CMS notes that in considering all services billed under the TIN of the ACO participant RHC or FQHC, the agency would include services that do not meet the definition of primary care services, and such services would not be limited to those provided by a primary care physician, as defined under current program rules. Therefore, a beneficiary could be furnished services in an RHC and FQHC only by a nurse practitioner, physician assistant, clinical nurse specialist, or any other practitioner in an RHC and FQHC and still be eligible for assignment to the ACO. While we support not requiring a physician visit for beneficiaries in RHCs/FQHCs as a requirement for assignment, we have concerns about treating all claims as primary care claims, which could result in unexpected assignment. The distinction between primary care and other services is important considering the statutory requirement to base assignment on the utilization of primary care services. We urge CMS to develop a way to identify FQHC/RHC primary care services to ensure appropriate assignment.

As we have commented previously to CMS, it is imperative that the agency establish a method to identify whether non-physician practitioners (NPPs) such as nurse practitioners (NPs), clinical nurse specialists (CNSs) and physician assistants (PAs) are primary care focused or if they are furnishing specialty care. While many of these NPPs are engaged in the delivery of primary care, which is

especially the case at FQHCs/RHCs, additional assurances are needed that this is the case. This would apply both with the assignment involving FQHCs/RHCs and would apply more broadly for all ACOs. Overall, we support CMS's efforts to properly involve FQHCs/RHCs in ACO assignment and request the agency move forward but also make methodological modifications as necessary to ensure ACO assignment is still based on primary care services furnished by primary care providers.

Proposed Changes to Quality Measures Validation Process

> **Key comment: NAACOS supports CMS's proposed changes to the quality measures validation process, however we urge the agency to lower the audit threshold to 70 percent.**

Proposal: CMS proposes adjustments to the quality reporting data validation process for ACOs, acknowledging that the changes CMS finalized in 2017 resulted in standards that may inappropriately penalize ACOs that make quality data reporting errors that are unrelated to care quality and instead are due to misunderstandings in the measure reporting requirements. Specifically, CMS proposes to set the audit match rate threshold based on the median match rate for ACOs audited in calendar year 2016 (80 percent). As proposed, if an ACO has a match rate below 80 percent, absent unusual circumstances, CMS would adjust the ACO's overall quality score proportional to the ACO's audit performance. CMS also proposes to amend the method by which the agency will adjust an ACO's overall quality score to reflect the ACO's audit performance. CMS proposes that for each percentage point difference between the ACO's match rate and the match rate considered passing the audit (80 percent as proposed), the ACO's overall quality score would be adjusted downward by 1 percent.

Comment: NAACOS noted its concerns with CMS's 2017 proposals to move to an overall audit match rate and to create audit-adjusted quality scores by multiplying the ACO's overall quality score by the ACO's overall audit match rate. This method of extrapolation is unfair and provides no recourse for ACOs. We are pleased to see CMS make proposals to refine this policy going forward. However, we urge CMS to finalize a 70 percent audit threshold to ensure only practices with true quality care issues are being targeted for an audit rather than those making errors due to misunderstandings in the measure reporting criteria. Making this modification will allow ACOs to benefit from learning opportunities through the audit process, allowing ACOs to change their processes to remedy errors resulting from a misunderstanding of the reporting requirements.

Initial MSSP Application Process

> **Key Comment: NAACOS supports CMS's proposal to reduce the Medicare Shared Savings Program initial application burden.**

Proposal: CMS proposes to remove the requirement to submit documents or narratives as part of the initial MSSP application and alternatively CMS would request these materials if additional information is needed.

Comment: We support ending the requirement to remove narratives from the initial application that historically have outlined required processes and patient-centeredness criteria, the ACO's organization and management structure, how the ACO would distribute shared savings, and how the ACO's proposed plan would achieve the specific goals of shared savings. We agree that the narratives, although at times may be helpful to reviewers, substantially increase application and review burden without lending commensurate value to the application. Therefore, we support removing these

requirements and request CMS to finalize its proposal. We also urge CMS to look even further at ways to simplify the initial application process.

Three-day SNF Waiver Application

> **Key Comment: NAACOS supports CMS's proposal to reduce the burden on applicants when applying for the SNF 3-day rule waiver application by removing extraneous requirements.**

Proposal: CMS proposes to reduce the burden of the SNF 3-day waiver by discontinuing the requirement to include narratives describing any financial relationships that exist between the ACO, SNF affiliates, and acute care hospitals. CMS also proposes to end the requirement that the applying ACO demonstrate that its intended SNF affiliates have a three or higher star rating under the CMS 5-star Quality Rating System.

Comment: We support CMS's proposal to discontinue narratives meant to describe the financial relationships between the ACO, SNF affiliates, and acute care hospitals. We recognize that the waiver does not protect any such relationship that would otherwise be liable under current fraud and abuse laws and that the narrative adds no value to the application. We also support ending the requirement for ACOs to demonstrate that each of their intended SNF affiliates has a three or higher star rating under the CMS 5-star Quality Rating System. Knowing that CMS application reviewers cross reference intended SNF affiliates with the most up to date star ratings, this step is unnecessary for applicants to demonstrate such information themselves. We strongly support making the SNF 3-day waiver more accessible and reasonable, and removing the requirements for narratives describing provider financial relationships and the duplicative work of demonstrating intended SNF affiliates' star ratings is a step in that direction. We also urge CMS to look even further at ways to simplify the SNF 3-day waiver application process.

Compliance with MSSP ACO TIN Exclusivity Requirement

> **Key comment: NAACOS supports CMS's proposed changes to the process for addressing ACO TIN overlap issues when exclusivity is required.**

Proposal: MSSP guidelines require an ACO participant Tax Identification Number (TIN) that submits claims for primary care services used to determine an ACO's assigned beneficiary population to be exclusive to one ACO. In rare instances as a result of CMS monitoring, the agency has discovered that ACO participant TINs that had been approved to participate in multiple ACOs subsequently began billing for primary care services used in assignment during a benchmark or performance year. In response, CMS requires the overlapping TIN to select one ACO and then the agency recalculates program methodologies including assignment and benchmarks as necessary for affected ACOs. CMS proposes that in these instances the agency would allow the TIN to remain on the ACO participant lists for all affected ACOs for the remainder of the performance year. To ensure that the TIN overlap does not inadvertently result in assignment of the same beneficiaries to multiple ACOs, CMS proposes the agency would exclude any claims for services furnished by the overlapping TIN from the assignment methodology when conducting final beneficiary assignment for any benchmark or performance year in which the TIN bills Medicare for services used in the assignment methodology. ACOs with overlapping TINs may be subject to compliance actions from CMS, such as having to submit a corrective action plan for how the ACO intends to address the overlap issue. Finally, the affected ACOs would be required to resolve the overlap prior to recertification of their ACO participant lists for the subsequent performance year.

Comments: As acknowledged by CMS, requiring a TIN to become exclusive during a performance year can have a significant effect on the ACOs that originally had the TIN on their participant lists. With the proliferation of more ACOs, these situations could occur more frequently in the future, and CMS should use an equitable approach that minimizes disruption to all involved. We feel the proposal accomplishes that goal, and we request CMS finalize it as proposed.

Other PFS Proposals

Approach to Misvalued Codes and Relative Value Units (RVUs)

> **Key comment: NAACOS cautions CMS not to relinquish its responsibility for establishing and updating RVUs and payment rates under the Medicare PFS to the RUC**

Proposals*:* CMS explains how the agency establishes work and practice expense (PE) RVUs for new, revised and potentially misvalued codes based on a review of information that generally includes recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. CMS assesses the methodology and data used to develop the recommendations submitted by the RUC and other public commenters, and the rationale for their recommendations. In this rule, CMS explains the agency plans to "shift our approach to reviewing RUC recommendations, especially as we believe that the majority of practitioners paid under the PFS, though not necessarily those in any particular specialty, would prefer CMS rely more heavily on RUC recommended values in establishing payment rates under the PFS" (p. 33987). Therefore, for 2018, CMS has generally proposed RUC-recommended work RVUs for new, revised and potentially misvalued codes.

Comments*:* We are concerned about CMS relinquishing its authority to the RUC. While we appreciate the work of the American Medical Association and the RUC, we have significant concerns that primary care is undervalued by the RUC, which tends to favor more procedural and specialty-based services. Therefore, should CMS step away from taking an active role in determining RVUs under its own PFS, the agency would be inflating the role of the RUC and thus underemphasizing primary care in the process. CMS states that the agency is proposing values based on its belief that the RUC generally considers the kinds of concerns CMS has historically raised regarding appropriate valuation of work RVUs. However, while the RUC may have considered these types of concerns, the committee's final recommendations do not necessarily strike the right balance across different provider types and services. It is CMS, not the RUC, that is responsible for setting RVUs under the PFS. Therefore, we urge CMS to retain an active role in evaluating information and data and setting reimbursement rates for services across the PFS.

Evaluation and Management (E/M) Services

> **Key comment: NAACOS supports efforts to simplify guidelines and documentation requirements for billing E/M services and urges CMS to focus on value.**

Proposal*:* CMS acknowledges the need to revise guidelines and documentation requirements for billing E/M services. The agency is seeking feedback on ways to reform the guidelines, reduce associated

burdens, and better align E/M coding and documentation with the current practice of medicine. The agency plans to focus initial changes to the guidelines on requirements related to a patient's history and physical exam, including consideration of removing documentation requirements for the history and physical exam for E/M visits, regardless of level. CMS also seeks comments on how to update medical decision-making guidelines.

Comments: We strongly support efforts to revise and alleviate burdens related to the guidelines and documentation requirements for E/M services, including reducing requirements related to the history and physical portions of the rules which are cumbersome and not directly tied to outcomes. As part of the process, CMS should also focus on revisions that support the overall goal of paying for value rather than paying for volume. For example, the agency should consider how to give credit for using team-based care and managing preventive interventions.

Chronic Care Management (CCM)

Key recommendations:

- **NAACOS recommends CMS finalize use of CPT codes in lieu of Medicare specific G-codes.**
- **NAACOS recommends CMS take further action to reduce regulatory burdens for furnishing CCM, including removal of face-to-face initiating visit requirements and certified EHR requirements.**

Proposals: CMS previously finalized payment for new care management codes including those related to complex CCM, behavioral health integration (BHI), and psychiatric collaborative care model (CoCM), which went into effect in 2017. CMS established four G codes for BHI (G0507) and psychiatric CoCM services (G0502, G0503 and G0504) and explained the agency would consider adopting associated Common Procedural Terminology (CPT) codes when those became available. For CY 2018, the CPT Editorial Panel is creating CPT codes 994X1, 994X2, 994X3, and 99XX5 to describe these services. Therefore, CMS proposes to use the CPT codes beginning in 2018. The agency would establish Relative Value Scale Update Committee (RUC) recommended RVUs with a minor refinement and the resulting values would match the current values for the existing G-codes. CMS also seeks public comment on ways the agency could further reduce the burden on reporting practitioners for CCM.

Comments*:* NAACOS has long supported CMS's effort to better serve beneficiaries with multiple chronic conditions and the providers who furnish their care through use of care management services. We appreciate the steps CMS has taken in recent years to introduce new care management codes and to simplify scope of service requirements for CCM. Care management services are essential for providing high quality, coordinated care for Medicare beneficiaries and for preventing adverse events, such as unnecessary hospital readmissions. By recognizing and reimbursing for these services, Medicare supports efforts by ACOs and practices to continue to enhance their focus on care coordination. Utilizing CPT codes, as opposed to similar but different G-codes, creates consistency across the industry and avoids confusion or potential inadvertent misuse of G-codes. Therefore, we support CMS's proposal to finalize the use of CPT codes for 2018.

In response to CMS's request for feedback on additional changes designed to alleviate burdens for providers furnishing CCM, we have two comments related to the initiating visit requirement and the use of certified Electronic Health Record (EHR) technology. For new patients or patients not seen within one year prior to the commencement of CCM, Medicare requires initiation of CCM services during a face-to-face visit with the billing practitioner (an Annual Wellness Visit [AWV] or Initial

Preventive Physical Exam [IPPE], or other face-to-face visit with the billing practitioner). In the 2017 final Medicare PFS, CMS removed this initiating visit requirement for existing patients seen within one year of the commencement of CCM. We urge CMS to remove the initiating visit requirement for all patients. This will provide more flexibility and allow ACOs to reach out to patients and obtain beneficiary consent in a number of different ways without being bound by the initiating face-to-face visit restrictions, which are an unnecessary regulatory burden inhibiting broader use of CCM and its related benefits.

As discussed in the regulatory relief comment section of this letter, we urge CMS to remove specific certification requirements for EHR technology. Further, we strongly recommend CMS provide that same flexibility for the purposes of meeting CCM requirements. CMS currently requires providers to record a patient's demographics, problems, medications, and medication allergies using certified EHR technology. We request CMS remove the requirement that CCM services be furnished using the edition(s) of certification criteria acceptable for the EHR incentive program as of December 31 of the calendar year preceding each CCM payment year. Purchasing and implementing an EHR demands considerable financial and administrative resources, and a high-quality EHR may serve an organization's needs for many years, even if it is not certified to the most recent CMS certification criteria. While an EHR can be an asset to furnishing CCM, it is unfortunate to prevent beneficiaries whose providers do not meet specific EHR certification requirements from accessing CCM services. We urge CMS to remove the requirement for a specific level of EHR certification, which is flexibility CMS has provided in relation to other Medicare programs and requirements. This flexibility is increasingly necessary as providers face many challenges and unforeseen circumstances related to EHR vendor certification and upgrading systems.

CCM in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

> **Key comments: NAACOS strongly supports allowing FQHCs and RHCs to provide and bill for a wide range of care management services and urges CMS to finalize this expansion using existing care management codes.**

<u>Proposal:</u> CMS proposes revisions to the CCM payment for RHCs and FQHCs and proposes requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018. The agency is responding to feedback about concerns that RHCs and FQHCs cannot bill for complex CCM, a policy which CMS finalized last year and is not proposing to change. The agency proposes to establish two new G-codes for use by RHCs and FQHCs:

- GCCC1 would be a General Care Management code for RHCs and FQHCs with the payment amount set at the average of the national non-facility PFS payment rates for CCM codes 99490 and 99487 and general BHI code G0507.
- GCCC2 would be a Psychiatric CoCM code with the payment amount set at the average of the national non-facility PFS payment rates for psychiatric CoCM codes G0502 and G0503.

Beginning on January 1, 2018, CMS proposes that RHCs and FQHCs would use the new codes and would no longer submit CPT 99490. Billing to these new codes would be permitted under general supervision requirements for incident-to claims, rather than requiring direct supervision.

<u>Comment:</u> FQHCs and RHCs play a pivotal role providing care, especially primary care, for beneficiaries in rural areas. We strongly support CMS finalizing changes to allow RHCs and FQHCs to provide and be reimbursed for providing a broad range of care coordination services, including those finalized for providers under the PFS. We recommend that rather than creating new G-codes that bundle various

care management services together, CMS finalize the actual codes used in the PFS for use by RHCs and FQHCs. That approach helps maintain consistency and avoids confusion for providers.

Telehealth Expansion

> **Key Comment: NAACOS supports CMS's proposal to expand the list of covered Medicare telehealth services.**

Proposal**:** CMS proposes to add the following codes to the list of covered Medicare telehealth services beginning in CY 2018 on a category one basis: counseling visit to discuss need for lung cancer screening using low dose CT, comprehensive assessment of and care planning for patients requiring chronic care management services, psychotherapy for crisis, administration of patient-focused health risk assessment instrument and administration of caregiver-focused health risk assessment instrument.

Comment: NAACOS supports CMS's proposal to expand the list of covered Medicare telehealth services. It is simply impossible to consistently and effectively coordinate care across the health system without fully utilizing telehealth and remote patient monitoring technologies. The Medicaid program and commercial payers are already significantly ahead of Medicare when it comes to embracing new technology that makes it possible for providers to succeed in value-driven arrangements and improve care for the beneficiaries they serve. NAACOS is fully supportive of expanding access to telehealth services when feasible and medically appropriate and these proposed codes meet that standard.

Excluding Interim-Payments Made Under Demonstrations, Pilots or Time-Limited Programs

> **Key comment: NAACOS urges CMS to create more transparency around the impact of overlapping programs such as episode payments on ACOs. CMS must disclose all related program costs, both interim and final, as well as a detailed explanation of the impact of these costs on the ACO.**

Proposal: CMS proposes to revise the applicable regulations to make clear that CMS would include only final individual beneficiary identifiable payments made under a demonstration, pilot or time-limited program in financial calculations related to establishing and updating benchmarks and determining performance year expenditures under the Shared Savings Program. CMS proposes that this policy would be applied to calculations that are necessary to determine ACO performance for the 2018 performance year and subsequent performance years. For ACOs that are in the middle of an agreement period when this revised policy takes effect, CMS would adjust the benchmarks for these ACOs at the start of the 2018 performance year and each subsequent performance year so that the benchmark for the ACO reflects the use of the same payment information that would apply in expenditure calculations for the performance year.

Specifically, CMS proposes that: (1) when establishing benchmarks for agreement periods before 2018, CMS will include all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time-limited program, (2) for agreement periods beginning in 2018 and subsequent years, CMS would only include individually beneficiary identifiable payments made under a demonstration, pilot or time-limited program that are final and not subject to further reconciliation, and (3) For the 2018 performance year and subsequent performance years in agreement periods beginning in 2015, 2016 and 2017, the benchmark would be adjusted to reflect only individually beneficiary identifiable final payments made under a demonstration, pilot or time-limited program.

Additionally, CMS proposes that when calculating expenditures for performance years before 2018, they would include all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time-limited program. When calculating expenditures for performance year 2018 and subsequent performance years, CMS would only include individually beneficiary identifiable payments made under a demonstration, pilot or time-limited program that are final and not subject to further reconciliation. To be consistent with treatment of claims-based payments, such final payments would have to be available in the separate CMS system by the end of the three-month claims run out period.

Comment: CMS believes that use of interim payments made under a demonstration, pilot or time-limited program could have an increasingly large effect on ACO benchmarks and performance year expenditure calculations in the future given widespread stakeholder interest in participating in alternative payment models and CMS interest in testing and expanding additional payment models that may lead to higher quality and more coordinated care at a lower cost to Medicare. CMS conducted a preliminary analysis which suggests that interim non-claims based payments (i.e., payments that are subject to reconciliation at a later date) made under a demonstration, pilot or time-limited program can fluctuate significantly from quarter to quarter and may not reflect the actual final reconciled payment amount. Therefore, CMS proposes that going forward, only final non-claims based payments made under a demonstration, pilot or time-limited program should be included in financial calculations related to benchmarks and performance year expenditures under the Shared Savings Program. NAACOS believes CMS should provide more information to ACOs on such payments and their impact on ACO spending both for interim-payments as well as final payments. CMS should provide this additional data in quarterly reports to ACOs. To date, CMS has not been sufficiently transparent in how the overlap of programs such as the Bundled Payments for Care Improvement Initiative (BPCI), Comprehensive Care for Joint Replacement (CJR) and others is impacting ACO spending. CMS has a responsibility to provide ACOs with detailed information on how other programs are affecting ACO spending. At a minimum, CMS must provide non-claims based payment information on a per program, per beneficiary basis.

The proliferation of demonstrations has the potential to significantly degrade ACO efforts if not handled appropriately. NAACOS has repeatedly advocated for CMS and the Innovation Center to exclude all ACO patients from any bundled payment demonstration or program. Absent this policy, it will become increasingly difficult for CMS to evaluate which program or entity is responsible for potential savings generated. Additionally, there are many operational difficulties that have resulted from program overlap, one being the ability for ACOs to understand the impact of other programs' spending on the ACO program's operations, expenditures and benchmarks. CMS must prioritize population health delivery models by excluding all ACO patients from bundled payments. Absent this policy, CMS must be fully transparent to ACOs by disclosing all related program costs and a detailed explanation of the impact of these costs on the ACO.

MACRA Patient Relationship Codes

> **Key comment: NAACOS urges CMS to continue to seek consultation from stakeholders on this important issue to further refine the proposed patient relationship categories to ensure the codes are ultimately useful and create reliable ways to attribute costs of care to clinicians without adding significant burden on providers.**

Proposal: The Medicare Access and CHIP Reauthorization Act (MACRA) requires CMS to develop care episode and patient condition groups, and classification codes for such groups for use in MIPS cost analysis. To facilitate the attribution of patients and episodes to one or more clinicians in MIPS, section 1848(r)(3) of the Act requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. The categories are required to include different relationships of the clinician to the patient and reflect various types of responsibility for and frequency of furnishing care. CMS posted the operational list of patient relationship categories on May 17, 2017, and they are as follows:

- Continuous/Broad Services
- Continuous/Focused Services
- Episodic/Broad Services
- Episodic/Focused Services
- Only as Ordered by Another Clinician

In this proposed rule, CMS seeks comment on these categories in preparation for potential subsequent revisions, which must be made by the agency no later than November 1, 2018. CMS also proposes that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018 would include the applicable HCPCS modifiers listed in Table 26 of the proposed rule, as well as the National Provider Identifier (NPI) of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner) on a voluntary basis. CMS plans to provide more clinician education on use of the modifiers during this time. CMS also clarifies the modifiers would also not be tied or related to intensity of services (evaluation and management services).

Comment: Though CMS's effort to categorize patient relationship codes is intended for use in calculating Merit-Based Incentive Payment System (MIPS) costs, NAACOS believes it is important to weigh in on this work, which, if implemented properly has the ability to result in improvements to the assessment of resource use generally. The categories as currently presented by CMS are too vague and therefore will not be useful in accurately and reliably categorizing appropriate patient relationships. Additionally, as drafted these categories do not adequately reflect team-based care, as multiple clinicians caring for a patient could easily define their relationship with the patient in the same manner (e.g., a primary care provider and specialist coordinating a patient's continuous care). For this reason, CMS should consider including a category to reflect an entire team of clinicians' relationships with an individual patient that could be used in conjunction with the individual clinician categories. CMS should also provide further guidance on distinguishing between continuous, episodic, and one-time interactions. We recommend CMS continue consulting with stakeholders on the most appropriate categories to attribute costs to clinicians. It is also important that CMS consider existing work flow and operations of clinicians and seek a solution that can be automated and/or embedded in existing health information technology systems so as to not add significant burden on providers. NAACOS urges CMS to continue to seek consultation from stakeholders on this important issue to further refine the proposed patient relationship categories to ensure the codes are ultimately useful and create reliable ways to attribute costs of care to clinicians without adding significant burden on providers.

2018 PQRS, Medicare Meaningful Use and Value-Based Payment Modifier Changes

> **Key comment: NAACOS is concerned that CMS's proposals to exempt additional clinicians from Physician Quality Reporting System (PQRS), Value Modifier and Meaningful Use**

penalties will discourage those clinicians who have already made a commitment to value-based care and invested time and resources towards making the shift to value-based care. We urge CMS to hold clinicians accountable and reward high-performing clinicians who have invested heavily in performance improvement and should therefore be rewarded for this investment, time, and effort.

Proposal: CMS proposes to retroactively modify the satisfactory reporting criteria for the calendar year 2016 reporting period for purposes of the 2018 PQRS, Value Modifier and Meaningful Use payment adjustments to better align with the Quality Payment Program (QPP) criteria. For PQRS, CMS proposes lowering the requirement from nine measures across three National Quality Strategy (NQS) domains, to six measures with no domain or cross-cutting measure requirement. CMS also proposes to remove the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS survey requirement for group practices comprised of 100 or more eligible professionals. Similarly, CMS proposes to change the reporting criteria for eligible professionals and groups who chose to electronically report clinical quality measures (CQMs) through the PQRS Portal for purposes of the Medicare Electronic Health Record (EHR) Incentive Program (Meaningful Use), changing the reporting criteria from nine9CQMs covering at least three NQS domains to six CQMs with no domain requirement. For the Value Modifier, CMS proposes to hold all groups and solo practitioners who meet the criteria to avoid the 2018 PQRS payment adjustment harmless from downward payment adjustments under quality tiering for the 2018 payment year. Additionally, CMS proposes to reduce the maximum upward adjustment under the quality-tiering methodology to two times an adjustment factor (+2.0x) for groups with 10 or more eligible providers (EPs).

Comment: As also noted in our comments to the agency on its proposals for the QPP, NAACOS is concerned that CMS's proposals to exempt additional clinicians from PQRS, Value Modifier and Meaningful Use penalties will discourage those clinicians who have already made a commitment to value-based care and invested time and resources towards making the shift to value-based care. We urge CMS to hold clinicians accountable and to reward high-performing clinicians who have invested heavily in performance improvement and should therefore be rewarded for this investment, time, and effort. It is critical that CMS maintain its commitment to transition providers and Medicare payments to improve the experience of care and the health of populations and to reduce per capita costs of health care. If the agency fails to follow-through on this promise, it discourages those who have been pioneers in the commitment to value-based health care and may lose momentum in encouraging those currently progressing along this continuum.

Medicare Diabetes Prevention Program (MDPP)

Key comment: NAACOS urges CMS increase reimbursement for MDPP services and allow for a modified enrollment and certification process for ACOs that have already been subject to a thorough vetting process by CMS.

Proposal: In the 2017 PFS final rule, CMS established a January 1, 2018 start date for the MDPP. In this proposed rule, CMS proposes MDPP services would instead be available on April 1, 2018 to provide more time for the agency to ensure MDPP suppliers have sufficient time to enroll in Medicare after the effective date of the final rule. CMS also makes proposals regarding eligibility criteria and payment for MDPP services. Specifically, CMS is proposing to pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. CMS proposes a maximum total performance payment amount per beneficiary for the set of

MDPP services of $810. Performance payments would be made to MDPP suppliers periodically during the course of a beneficiary's MDPP services period based upon a number of factors. Additionally, CMS proposes numerous MDPP supplier enrollment, documentation and compliance requirements.

Comments: NAACOS strongly supports structured health behavior change programs such as the MDPP, which are designed to manage and prevent high cost, chronic conditions such as diabetes. Many ACOs refer patients to disease prevention programs (DPPs) in their communities, and we support CMS's expansion of the DPP. However, the proposed MDPP reimbursement is too low for Medicare providers who have more significant costs such as practice expenses including medical office rent, supplies, equipment and support staff. As proposed, directly providing the MDPP services would not be cost effective for many ACOs, and we recommend increased reimbursement for this program to ensure access to it and its services.

We also urge CMS to limit documentation and billing requirements, which are often a hindrance to providers participating in an otherwise attractive program which benefits patients. Additionally, we recommend the agency allow for a streamlined enrollment process for ACOs, which are already thoroughly vetted by CMS via their ACO application process, as well as the individual group practices, hospitals and clinicians of which an ACO is comprised that all go through an in-depth Medicare enrollment process in order to participate and bill Medicare for services they furnish. These providers should not have to go through the same enrollment and certification process as a community-based organization that does not traditionally deal with Medicare.

Comments on Reducing Regulatory Burdens for Providers

High Priority

Overlap of Medicare ACO Programs and Other CMS/CMMI Programs

> **Key comment: NAACOS urges CMS to exclude all ACO patients from bundled payment programs and demonstrations.**

Comment: The Innovation Center (CMMI) has released numerous demonstrations and pilots, many of which overlap with the goals of the ACO program. This overlap creates operational challenges and confusion and pits specialty-focused bundled payments against population health focused payment and delivery models like ACOs. NAACOS urges CMS to address the problematic interactions between the MSSP and other CMS/Innovation Center programs, which lead to negative unintended consequences that undermine ACOs by excluding all ACO patients from other payment models. For example, when one patient is attributed to a bundled or episode payment he or she can also be simultaneously attributed to the ACO, adding to the ACO's costs and creating confusion due to this overlap. What's more, CMS gives precedence to bundlers, assigning patients first to a bundled payment episode while still holding the ACO accountable for that patient's costs of care. Under current CMS policy, a bundled payment participant maintains financial responsibility for the bundled payment episode of care. Any gains or losses during that episode are linked to the bundled payment participant and are removed from ACO results during year-end financial reconciliation. It is imperative that CMS reverse this policy and instead exclude ACO patients from bundles unless a collaborative agreement between the bundler and the ACO is in place. Without such changes, CMS risks the vitality of the ACO program which will see diminished savings opportunities resulting from this overlap.

Extended Track 1 Participation

> **Key comment: NAACOS strongly requests that CMS allow ACOs to remain in MSSP Track 1 for more than two agreement periods.**

Comment: As a portion of total 2017 Medicare ACOs, ACOs in two-sided risk models only represent around 15 percent, and within just the MSSP that portion is less than 9 percent. The one-sided Track 1 remains by far the most popular option, and from 2012 to 2016 the rate of adoption of Track 1 has been four times the adoption rate of two-sided models. However, ACOs may only remain in Track 1 for two agreement periods before having to move to a two-sided risk model or drop out of the program. There are 114 ACO in their second and final Track 1 agreement period, representing nearly a third of ACOs in the MSSP. ACOs remain in Track 1 for a number of reasons including the amount of risk required in two-sided models, challenges obtaining financial backing or securing loans, and concerns about the effect losses would have on providers and the beneficiaries they serve. These challenges are often exacerbated for those in rural areas and safety-net providers, which care for some of the most vulnerable patient populations.

As recently identified in a study by the Office of Inspector General (OIG), ACOs are helping to bend the cost curve for Medicare while also improving quality. Specifically, the OIG report explains that most ACOs in the first three years of the MSSP reduced Medicare spending compared to their benchmarks, achieving a net reduction of nearly $1 billion. Requiring ACOs to assume risk if they are not ready will result in these ACOs dropping out of the MSSP. This unintended consequence would result in providers in ACOs no longer having much of an incentive to help bend the cost curve in Medicare, which would mean CMS foregoes an opportunity to generate significant savings over time. We urge CMS to modify regulations at 42 CFR § 425.600(b) to permit MSSP ACOs that meet criteria related to generating savings or improving quality to remain in Track 1 for more than two agreement periods.

Care Coordination Data

> **Key comment: NAACOS requests that CMS provide ACOs access to valuable and actionable real-time data needed for successful care coordination.**

Comment: 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. 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.

Risk Adjustment

> **Key comment: NAACOS urges CMS to address ongoing concerns and limitations of MSSP risk adjustment.**

Comment: 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 will only *decrease* risk scores for improved health status and will not 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 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.

Advanced APM ACO Models

> **Key comment: NAACOS urges CMS to allow MSSP Track 1 to qualify as an Advanced APM under the MACRA QPP**

Comment: NAACOS supports CMS's inclusion of the MSSP Tracks 2 and 3 and the Next Generation ACO Model on the list of Advanced Alternative Payment Models (APMs) under the MACRA Quality Payment Program (QPP). However, it is imperative to recognize the important work of ACOs in shifting the industry to value-based care by allowing all ACOs, including those in MSSP Track 1, to qualify for Advanced APM bonuses. ACOs in these models are dedicated to enhancing the experience of care, improving quality and the health of populations, and reducing per capita costs of health care. We urge CMS to develop a mechanism to account for the substantial investments ACOs make (on average, $1.6 million annually) and include these in the determinations of meeting Advanced APM risk under MACRA. It is critical to the future success of ACOs that CMS modify regulations at 42 CFR §414.1410 and §414.1415 to designate MSSP Track 1 as an Advanced APM and allow ACO investments to count towards meeting QPP risk requirements.

Rebased Benchmark Methodology

> **Key comment: NAACOS urges CMS to modify MSSP rebased benchmarking policies to address methodological flaws.**

Comment: 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. 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. 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.

Payment Rule Waivers

> **Key comment: NAACOS recommends CMS to expand the use of payment rule waivers across ACO models by allowing waivers related to the Skilled Nursing Facility (SNF) 3-day Rule, telehealth, home health and primary care co-payments.**

Comment: 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 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.

Reconciliation Adjustment

> **Key Comment: NAACOS urges CMS to permit individual ACOs to appeal a payment determination if they feel that the calculation was made in error**.

Comment: Current regulation allows for CMS to reopen ACO reconciliation determinations at its own discretion. This discretion is not harmed by providing ACOs with the ability to appeal a payment determination that may have been made in error. In fact, permitting individual ACO appeals would help prevent future redeterminations and reduce the administrative burden associated with such reopenings. An ACO's appeal may serve to alert CMS to a larger issue, which can be solved timely and more efficiently than one discovered years down the road. Further, we urge CMS to be transparent with its process for determining "good cause." We therefore urge CMS to update 42 CFR §425.315 so that individual ACOs may appeal payment determinations and requests all determinations of "good cause" are transparent and forthcoming.

Program Transparency

> **Key comment: NAACOS requests that CMS improve transparency for ACO program methodologies.**

Comment: 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. 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.

Track 1+

> **Key comment: NAACOS urges CMS to make Track 1+ a permanent part of the MSSP and allow indefinite participation, which meets two-sided requirement.**

Comment**:** NAACOS strongly supports the introduction of Track 1+, which is a two-sided ACO model with risk levels more appropriate for providers. Track 1+ is an important step to support the long-term viability of the ACO model and represents a missing piece of the current Medicare ACO portfolio. Under current program guidance, CMS only allows ACOs to participate in Track 1+ for between two and five years, depending on ACO's Track 1+ start date, before having to take on greater risk in other ACO tracks/models. However, many ACOs that participate in Track 1+ will not be prepared to assume greater levels of risk in other ACO models in the future. Further, Track 1+ risk levels meet the nominal risk criteria under the MACRA QPP and should be sufficient for long-term participation. As such, participation in Track 1+ should not be restricted to a specific number of agreement periods. We also

request that CMS increase the shared savings rate for Track 1+ from 50 to 60 percent. This increase would match the shared savings rate for Track 2 instead of Track 1, which is appropriate given the increased risk ACOs in Track 1+ are assuming. Therefore, we urge CMS to allow long-term participation in Track 1+ and increase the shared savings rate to 60 percent, which will reinforce ACOs' commitment to improving quality and reducing expenditures, therefore benefitting the Medicare Trust Fund and the ACO's beneficiary population.

Reducing Quality Burdens for ACOs

> **Key comment: NAACOS urges CMS to reduce the number of ACO quality measures and to place a focus on outcomes measures over process measures, thereby also reducing quality reporting burdens.**

Comment: ACOs are currently evaluated on 31 quality measures, while other programs use significantly fewer measures such as the MIPS, which requires clinicians to report on six quality measures. Most of these measures are reported through the (GPRO) 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.

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.

Physician Self-Referral Law

> **Key comment: NAACOS urges CMS and Health and Human Services (HHS) to provide additional flexibility under the physician self-referral law for ACOs.**

Comments: For several years, health care 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-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.

Allowing ACOs to Increase Beneficiary Engagement

> **Key comment: NAACOS urges CMS to provide new opportunities for ACOs to increase beneficiary engagement through incentives for beneficiaries choosing high quality, efficient providers that work collaboratively with the ACO.**

Comment: 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 (MA) 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 MA plans to increase beneficiary engagement through incentives for beneficiaries choosing high quality, efficient providers that work collaboratively with the ACO.

Medium Priority

ESRD Benchmark Category

> **Key comment: Modify the process to classify ACO beneficiaries with End Stage Renal Disease (ESRD) for ACO benchmarks.**

Comment: The MSSP classifies beneficiaries into four categories, one of which is for beneficiaries with ESRD. This category often has a significant effect on ACO benchmarks because ESRD beneficiary expenditures are typically considerably higher than expenditures for those without ESRD. Beneficiaries who apply for Medicare based on their ESRD status are included in the ESRD beneficiary category, and typically the only beneficiaries to do this are those who only qualify for Medicare based on their ESRD status. Beneficiaries, who have existing Medicare coverage based on their age but who develop ESRD, rarely update their beneficiary eligibility status since they have no reason to do so as they can access ESRD treatment as part of their normal Medicare benefits. The resulting impact on ACOs is that these beneficiaries are not properly classified for purposes of the ACO benchmark. This can inappropriately drive up costs under other benchmark categories and ultimately skew ACO benchmarks. Improper beneficiary classification unfairly harms ACO performance by distorting expenditures and benchmark

evaluations in a manner that is not reflective of reality. NAACOS strongly recommends CMS address this beneficiary classification flaw by automatically assigning beneficiaries to the ESRD beneficiary category based on claims data, rather than exclusively rely on the Social Security Administration's classifications, which are often not updated or accurate.

Track 1 Early Advancement

> **Key comment: NAACOS recommends CMS allow ACOs that are ready to move into a two-sided risk model to do so at the start of any performance year and not require them to wait until the start of their next agreement period.**

Comment: Currently, ACOs may only switch to MSSP Tracks 2 or 3 at the start of a new three-year agreement, and once that period begins they are locked in to their decision until their next agreement. Track 1 ACOs should be allowed to advance to a two-sided ACO model during an agreement period. This would be in line with CMS's goal of moving ACOs to two-sided models and would allow more ACOs to participate in an Advanced APM in Medicare QPP. CMS already permits early advancement to Track 1+ and the Next Generation ACO Model and should permit early advancement to Track 2 and 3.

Beneficiary Assignment

> **Key comment: NAACOS requests that CMS allow ACOs to have the option of choosing prospective or retrospective beneficiary assignment.**

Comment: For Tracks 1 and 2, CMS uses preliminary prospective beneficiary assignment with final retrospective beneficiary assignment. For Track 3, CMS uses prospective beneficiary assignment, which relies on the same stepwise assignment methodology used for Tracks 1 and 2 but assigns beneficiaries to Track 3 ACOs prospectively at the start of the performance year. Under this method, there is no retrospective reconciliation resulting in the addition of new beneficiaries at the end of the performance year. This approach provides a more predictable benchmark and a more stable beneficiary population on which the ACO can focus its efforts. Certain ACOs, such as a small ACO worried about dropping below the 5,000-beneficiary minimum may prefer a model where it can add beneficiaries throughout the year, and would thus prefer the retrospective assignment model. However, other ACOs would likely prefer a prospective model, which would help them stabilize their beneficiary population and thus avoid volatile benchmark changes. NAACOS urges CMS to continue to foster ACOs' success by permitting all MSSP models the option of choosing prospective or retrospective beneficiary assignment.

Fraud and Abuse

> **Key comment: NAACOS recommends that CMS allow ACOs direct access to CMS program integrity to report suspected fraud and abuse.**

Comment: Value-based delivery models such as ACOs have a unique vantage point and the properly aligned incentives to identify and ultimately report fraud. On average, a Medicare ACO is assigned 17,000 lives and includes hundreds of clinicians. Its success depends on an ACO continuously monitoring its expenditures. Because ACOs are held responsible for the total cost of care for their assigned beneficiaries, ACOs are also monitoring services rendered by clinicians outside the ACO and keep an eye on reimbursements completely removed from their own financial interests other than to achieve shared savings. That close attention to beneficiaries and the services they are accessing through Medicare provides ACOs a frontline perspective to identify and report suspicious activity but

have no direct access to CMS program integrity. NAACOS encourages CMS to better serve beneficiaries and American taxpayers by creating a direct channel for ACOs to report suspected fraud and abuse.

Reducing regulatory burdens for ACOs in MIPS

> **Key comment: NAACOS urges CMS to reduce regulatory burdens to the greatest extent possible for ACOs also evaluated under MIPS.**

Comment: CMS currently excludes Track 1 ACOs from the Advanced APM category of the QPP. Therefore, Track 1 ACOs are subject to both MSSP requirements as well as QPP requirements, specifically MIPS requirements. Because Track 1 ACOs are subject to both MSSP and MIPS requirements, it is incumbent upon CMS to reduce the burden ACOs face in MIPS to reduce administrative burdens and costs associated with complying with two sets of separate program criteria, all of which aim to measure the ACO's performance on quality and reducing costs. ACOs are accountable for a patient's total cost of care, regardless of which track of the MSSP program they participate in. Therefore, it is duplicative and unnecessary to hold ACOs accountable in both MIPS performance as well as MSSP performance. At this time, CMS' current policy does not recognize Track 1 ACOs as Advanced APMs; and, therefore, they are concurrently subject to MIPS requirements. Until and unless this policy is changed, it is incumbent upon CMS to reduce the regulatory burden on ACOs to comply with MIPS requirements to the fullest extent possible. This includes making all program criteria and scoring methodologies for ACOs specifically accessible and transparent.

Data User Agreement (DUA) Requirements

> **Key Comment: NAACOS requests CMS revise MSSP DUA requirements by providing clarification on permissible use of data and removing the approval process to add a party to a DUA.**

Comment: 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.

Repayment Mechanism Requirements

> **Key comment: NAACOS recommends that CMS remove repayment mechanism requirements for two-sided ACOs.**

Comment: 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.

TIN Changes from Mergers

> **Key Comment: NAACOS recommends CMS address the effect of provider mergers that result in a TIN change that can impact ACO beneficiary assignment during a performance year.**

Comment: When practices undergo a merger or acquisition, their TIN often changes. These mergers/acquisitions happen throughout the year, which can be problematic for ACOs because they cannot add new TINs during the performance year and must wait until the beginning of the next performance year for TIN changes to go into effect. During a merger/acquisition with a TIN change, an ACO can lose beneficiary attribution if their participant TIN no longer exists, even if the TIN wants to remain part of the ACO. In this instance, the TIN rejoins the ACO the following performance year, causing a disruption during the year of the merger/acquisition. Smaller ACOs can be at risk of falling under the 5,000-beneficiary threshold to participate in the MSSP and all ACOs face fluctuations in assignment and expenditures. CMS should recognize this issue and work with stakeholders to find a solution to best address TIN fluctuations resulting from mergers/acquisitions during a performance year.

Simplify ACO Marketing Requirements

> **Key comment: NAACOS urges CMS to simplify ACO marketing requirements by removing the requirement to submit internal provider facing materials to CMS.**

Comments: 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 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.

Information from PECOS

> **Key comment: NAACOS requests that CMS provide detailed information on Tax Identification Number (TIN)/National Provider Identifier (NPI) data for ACO participant TINs at least quarterly to ACOs and upon request during a performance year.**

Comments: Participation in the MSSP requires all suppliers in a TIN to participate, and those individuals are essential in driving critical program functions such as beneficiary assignment and determining expenditures for which the ACO is held accountable. As new clinicians join a new TIN or leave a TIN, it is essential that they, or their respective group practices, update the related Medicare enrollment records in the Provider Enrollment, Chain, and Ownership System (PECOS). The requirement to update PECOS to reflect changes related to Medicare enrollment or reassignment of billing privileges is long-standing and goes beyond MSSP requirements. While CMS and the health care industry have made strides in recent years to make these updates in a more timely and routine fashion, there remains a large proportion of outdated information in PECOS. This is often the case when a clinician's name/association with a group practice is not terminated following his or her departure from the organization. ACOs work closely with their participant TINs to ensure those updates are made in a timely manner, which supports the ACO's effort to have the correct clinicians used for MSSP participation and supports compliance with CMS's requirements and goals to have timely, correct information in PECOS. However, ACOs with multiple TINs are not permitted to directly view or make updates in PECOS on behalf of their participant TINs. ACOs only receive an annual report showing detailed information from PECOS for their participant TINs, including the legal business names and exact NPIs in each TIN and the effective and termination dates for individual clinicians within those TINs. ACOs need access to this information on a more regular basis. Providing this information would not only help ACOs but would benefit CMS as it would encourage the ACO TINs to keep their PECOS information up to date and clean up the PECOS database. Therefore, we urge CMS to provide to ACOs detailed information from PECOS on a quarterly basis and to provide that to an ACO at any time upon request during the performance year.

Clarify ACO Compliance Requirements

> **Key comment: NAACOS urges CMS to more clearly articulate what compliance training is required of ACOs, including who must complete the training and what constitutes sufficient training.**

Comments: ACOs have a plethora of compliance and documentation requirements they must adhere to, both for purposes of the ACO as well as other state and federal requirements. Therefore, CMS must clearly articulate to ACOs what compliance training is required for the purposes of the ACO program specifically, as well as who must complete the training and what constitutes sufficient training. The lack of clarity in this area creates confusion and is a barrier for participation in the ACO program. Therefore, NAACOS urges CMS to more clearly articulate to ACOs what compliance training is required for the purposes of the ACO program specifically, as well as who must complete the training and what constitutes sufficient training.

Remove Electronic Health Record (EHR) Certification Requirements

> **Key comment: NAACOS urges CMS to remove requirements for ACOs to use specific certified EHR products and instead allow ACOs to choose the product that is best for their organization.**

Comments: 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

We support many of the proposals in the proposed 2018 Medicare PFS and request that CMS considers our feedback related to these and other proposals for which we are requesting modification. ACOs play an integral role in moving the health system into a new era of high quality, integrated care designed to benefit patients, and reduce unnecessary costs and utilization. However, the ability of ACOs to succeed will depend largely on the policies CMS finalizes, and we urge the agency to consider the feedback presented from the ACO community outlined in this letter. Should you want to further discuss any of our recommendations, please contact Allison Brennan, Vice President of Policy, at abrennan@naacos.com. Thank you for your consideration of our comments.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
National Association of ACOs