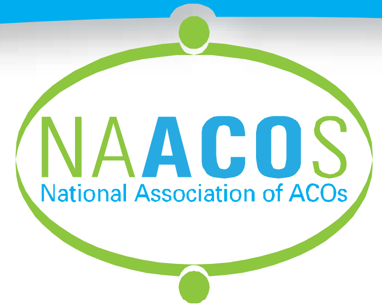

September 6, 2016

Andrew Slavitt
Acting 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-1654-P) Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Proposed Rules

Submitted on September 6, 2016 via www.regulations.gov

Dear Acting Administrator Slavitt:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments on the rule, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Proposed Rules" (file code CMS-1654-P), as published in the July 15, 2016 Federal Register. We appreciate the opportunity to comment on a number of important proposals outlined in this proposed Medicare Physician Fee Schedule (PFS), particularly those related to the Medicare Shared Savings Program (MSSP), enhancements to primary care payments, and implementation of the Medicare Access and CHIP Reauthorization Act (MACRA).

NAACOS is the largest association of Medicare ACOs, representing over 3.1 million beneficiary lives through 210 MSSP, Next Generation, and Pioneer 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 for Medicare beneficiaries, reduce healthcare costs, and improve quality in the Medicare program.

ACOs represent a refined approach to the delivery of health care and were created through a bipartisan effort to facilitate coordination and cooperation among providers to improve the quality of care and to reduce unnecessary costs. To ensure the strength and long-term viability of the ACO model, this letter urges CMS to finalize a number of proposals and modify certain proposals in the final 2017 Medicare PFS.

Summary of Key Recommendations

Specifically, in the final 2017 Medicare PFS, NAACOS urges CMS to:

- **Finalize MSSP voluntary beneficiary alignment for ACOs in all tracks using an automated approach and put safeguards in place to ensure a relationship between the beneficiary and their "main doctor"**
- **Not finalize the expansion of the quality measure related to the degree of Certified EHR Technology (CEHRT) use by all eligible clinicians (ECs) under the MACRA Quality Payment Program (QPP) and make this measure pay for reporting in all performance years**
- **Maintain the current MSSP quality measures validation audit process**
- **Finalize proposals to align ACO quality measure reporting with the quality reporting requirements under the Merit-Based Payment Incentive System (MIPS)**
- **Finalize CMS's proposal to provide flexibility to clinicians who may be penalized under the Physician Quality Reporting System (PQRS) and the Value-Based Payment Modifier (VM) should their ACO fail to successfully report quality measures on their behalf by allowing these providers to report separately from the ACO in order to avoid penalties**
- **Finalize the clarification that a two-sided ACO which falls below 5,000 assigned beneficiaries at the time of financial reconciliation would maintain eligibility for shared savings/losses and would maintain the Minimum Savings Rate/ Minimum Loss Rate (MSR/MLR) initially selected by the ACO**
- **Finalize new care coordination and complex chronic care management (CCM) services and reduce burdens associations with CCM services**
- **Limit administrative burdens related to a global surgical services data collection effort by using a sample of providers and use an appropriate sample size of Medicare ACOs for the ACO-specific survey**

Medicare Shared Savings Program Proposals

Voluntary Beneficiary Alignment

CMS Proposal: CMS proposes to modify the MSSP beneficiary assignment algorithm to allow beneficiaries to designate an ACO professional as responsible for their overall care. This designation would result in the beneficiary being assigned to that ACO, thus taking precedence over assignment to another organization based on where a beneficiary receives a plurality of their primary care services. CMS proposes using an "automated" approach under which the agency would determine which healthcare provider a beneficiary believes is responsible for coordinating his or her overall care (their "main doctor") using information collected from beneficiaries through a CMS system such as MyMedicare.gov, 1-800-Medicare or the Physician Compare website.

CMS would notify beneficiaries of the opportunity to designate their main doctor through beneficiary outreach and ACOs would be permitted to encourage this as well. Should the agency finalize an automated approach, it proposes to do so for the 2018 performance year for ACOs in all MSSP tracks. CMS proposes Track 1 and 2 ACOs would have information from voluntary alignment updated on a quarterly basis and for Track 3 ACOs,

this information would be updated on an annual basis. CMS proposes that if a beneficiary voluntarily aligns with a provider or supplier whose services would be considered in assignment but who is not participating in an ACO as an ACO professional, the beneficiary would not be eligible for alignment to an ACO, even if the beneficiary would have otherwise been assigned to an ACO under a claims-based approach. CMS seeks comments on whether ACOs should be able to choose whether to opt into/out of voluntary alignment.

Alternatively, if CMS implements a "manual" process for MSSP similar to that used for Next Generation and Pioneer ACOs, the agency proposes to, at least initially, limit voluntary alignment to Track 3 ACOs. It would be available starting for the 2018 ACO performance year but only for Track 3 ACOs in their second or subsequent performance years in 2018 or beyond. CMS also proposes that under a manual approach ACOs would only be permitted to contact beneficiaries that were aligned prospectively to the ACO in the current or prior years.

NAACOS key recommendations:

- **NAACOS urges CMS to offer a voluntary beneficiary alignment process for all MSSP ACOs, regardless of track.**
- **NAACOS strongly recommends using an automated approach to collect beneficiary attestation information, provided certain safeguards are put in place to ensure a relationship between the beneficiary and ACO.**
- **NAACOS recommends that CMS incorporate the option for prospective beneficiary assignment for all ACOs.**

Additional comments: After years of advocating for CMS to incorporate a voluntary beneficiary attestation process into the MSSP assignment methodology, we are very pleased to see this proposal. Providing beneficiaries with the opportunity to align voluntarily with an ACO would balance the important considerations of beneficiaries' freedom to choose their providers, with ACOs' interest in reducing patient turnover or "churn", thus providing a more defined and stable beneficiary population up front. This, in turn, would allow ACOs to better target their efforts to manage and coordinate care for beneficiaries whose care they will ultimately be held accountable for. In addition, allowing beneficiaries to attest to the provider they want to manage their care may help increase beneficiary engagement in that care.

We recognize the challenges associated with the "manual" approach CMS uses with Next Generation and Pioneer ACOs. This process has been very cumbersome, and as CMS points out in the proposed rule, only half of eligible ACOs have pursued voluntary alignment because of these cost/benefit concerns. Therefore, we support using an automated approach for voluntary alignment, which would ease administrative burdens on ACOs and CMS and allow for more robust participation. However, it is critical for CMS to put in place appropriate safeguards to ensure beneficiaries are only aligned to ACOs with which they have a true relationship. It is important this policy helps to ensure an ongoing relationship with a primary provider. **We strongly support voluntary alignment, but we urge CMS to allow only designations from voluntary alignment to override assignment from claims data when the ACO professional or a colleague billing under that Tax Identification Number (TIN) has provided at least one primary care service during the previous or current calendar year.** CMS mentions the beneficiary having at least one primary care service with an ACO professional as a requirement for *establishing* the initial alignment. Specifically, on page 46436:

> "Beginning in performance year 2018 beneficiaries that have voluntarily aligned with an ACO by designating an ACO professional whose services are used in assignment as responsible for coordinating their overall care will be added to the ACO's list of assigned beneficiaries, for a performance year under the following conditions:
>
> - The beneficiary must have had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under §425.20

of this subpart or who has one of the primary specialty designations included in §425.402(c).

- The beneficiary must meet the assignment eligibility criteria established in §425.401, and must not be excluded by the criteria at §425.401(b).
- The beneficiary must have designated an ACO professional who is a primary care physician as defined at §425.20 of this part, a physician with a specialty designation included at §425.402(c) of this subpart, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.
- The designation must be made in the form and manner and by a deadline determined by CMS."

However, on page 46436 CMS goes on to say:

> "A beneficiary that meets the eligibility criteria may voluntarily align with a practitioner participating in an ACO, become aligned to the ACO, but subsequently choose to receive all his or her primary care from a practitioner that is unaffiliated with the ACO. In this case, the beneficiary would continue to be assigned to the ACO based upon the beneficiary's designation of an ACO professional as their "main doctor" for the remainder of the performance year under the manual process, and indefinitely until the beneficiary changes his or her designation under the automated process." (emphasis added)

We appreciate that voluntary alignment would in no way limit a beneficiary's choice of provider, and we support not requiring the beneficiary to update alignment information annually. However, there must be safeguards in place to negate voluntary alignment if claims data show a beneficiary never establishes or no longer has a relationship with a provider. CMS addresses this situation by explaining "we believe these scenarios, which may involve undesirable effects on the accuracy of beneficiary alignment, can be limited when beneficiaries are provided sufficient information about the importance of keeping the designation of their "main doctor" up to date" (p.46436). While CMS acknowledges this challenge, the agency does not address how beneficiaries will be provided "sufficient information" about the importance of keeping this information up to date. Beneficiaries that don't update their information over time would face no negative consequences, but ACOs would be held responsible for the costs of this care even if they have not furnished services to that beneficiary for years. This situation is of great concern, as is a situation where organizations without an existing relationship reach out to beneficiaries asking them to designate their providers as their "main doctor." Both of these must be avoided.

Currently, in order for a Medicare fee-for-service beneficiary to be eligible to align voluntarily with a Next Generation ACO for performance year two (Next Generation ACO contract year 2017), the beneficiary must have had at least one paid claim for a qualified evaluation and management service on or after January 1, 2014, with an entity that was a Next Generation Participant during performance year one, among other requirements. Similarly, CMS explains that should the agency use a manual approach, an ACO would only be permitted to contact beneficiaries that were aligned prospectively to the ACO in the current or prior years. These limitations for the manual approach are designed to restrict voluntary alignment to ACO professionals with whom a beneficiary has a documented relationship. **We request CMS put in place similar parameters with the automated approach in order to prevent establishing or maintaining inaccurate and/or outdated alignments. Specifically, we recommend using an automated approach that overrides the existing assignment methodology only when a beneficiary has at least one qualified primary care service (based on the existing services used for MSSP assignment) during the previous or current performance year with an ACO professional as defined under Step 1 or Step 2 of MSSP assignment.**

CMS proposes Track 1 and 2 ACOs would have information from voluntary alignment updated on a quarterly basis and for Track 3 ACOs, this information would be updated on an annual basis. We support the annual update for Track 3 ACOs, which have prospective assignment and don't receive updated lists throughout the

year. For Track 1 and 2 ACOs, we recommend that alignments indicated in the previous year or the first three months of the year would be effective for that year and those indicated later in the year would go into effect in the next calendar year. This timing would allow ACOs to identify new beneficiaries aligned to their ACO on the quarterly reports beginning with the first or second quarter reports, thus enabling the ACO to identify and focus efforts on these beneficiaries. It would avoid situations where a beneficiary aligns with the ACO later in the year but the ACO does not receive that information until their last quarterly report or after the end of the year. At that point, the ACO would not be able to target the beneficiary's care and make a meaningful difference for the year.

Further, we strongly recommend CMS allow ACOs in all tracks to utilize payment waivers, such as those related to Skilled Nursing Facility (SNF) care, telehealth, home health and primary care co-pays, for all beneficiaries that voluntarily align to the ACO. CMS's rationale for limiting use of these waivers has been based on not knowing which beneficiaries would be ultimately attributed to a Track 1 or 2 ACO, which would not be the case for beneficiaries that voluntarily align.

CMS seeks comment on whether voluntary alignment should be optional for ACOs, and we support allowing ACOs to choose to utilize voluntary alignment. CMS also requests feedback on whether it is appropriate for beneficiaries who would be retrospectively assigned to an ACO, as with MSSP Tracks 1 and 2. We feel voluntary alignment is appropriate for ACOs that have either retrospective or prospective assignment. While not proposed in this rule, we also reiterate our long-standing request that CMS allow the option for prospective assignment for ACOs in all MSSP tracks. Under a prospective beneficiary assignment 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 stable beneficiary population and a more predictable benchmark. **We support allowing ACOs in all MSSP tracks to have the option of choosing prospective or retrospective assignment**.

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. Advanced ACOs typically employ data analysis and beneficiary engagement techniques from the start of the performance period on a population for whom they know they are responsible. Further, providing a choice between retrospective and prospective assignment would benefit Track 1 and 2 ACOs that may prefer to become accustomed to prospective assignment or may be eligible for payment waivers. For example, under Track 3, CMS permits a waiver of the SNF 3-Day Rule, which allows Track 3 ACOs to receive payment for SNF services when a prospectively assigned beneficiary is admitted to a SNF without a prior 3-day inpatient stay. In its final June 2015 MSSP rule, CMS explained its rationale for limiting the waiver to Track 3 was based largely on the fact that was the only track that has prospective assignment. By allowing ACOs in all tracks to select prospective assignment, CMS could provide broader use of payment waivers, as the population to which the waivers would apply would be easier to define. **In sum, in addition to CMS's proposed changes related to voluntary alignment, we urge the agency to allow ACOs in all tracks to have the option of utilizing voluntary alignment as well as the option to select prospective beneficiary assignment.**

Quality Reporting

CMS Proposal: Changes to the ACO Measure Set

CMS proposes numerous changes to the MSSP quality measure set to better align with the Core Quality Measures Collaborative measure recommendations, including to replace ACO measure 39 (Documentation of Current Medications in the Medical Record) with the previously used ACO measure 12 (Medication Reconciliation) in the Care Coordination/Patient Safety domain. CMS proposes to also add two new measures

to the ACO measure set. The first, ACO measure 44 (Use of Imaging Studies for Low Back Pain) would be added and analyzed using administrative claims data. The second new proposed measure is ACO measure 43 (Ambulatory Sensitive Condition Acute Composite), which would be risk-adjusted for demographic variables and comorbidities and phased into pay for performance after two years as a pay-for-reporting measure. This measure is Agency for Healthcare Research & Quality (AHRQ) Prevention Quality Indicator 91.

CMS also makes a proposal to change the specifications of ACO Measure 11 (Percent of Primary Care Physicians Who Successfully Meet Meaningful Use Requirements) to align with the QPP proposals made in the MACRA Notice of Proposed Rulemaking (NPRM) published in the May 9, 2016 Federal Register, "Medicare Program; Merit-Based Incentive Payment System [MIPS] and Alternative Payment Model [APM] Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule" (MACRA NPRM). CMS proposes specifically to change the specifications of the measure to assess the ACO on the degree of Certified EHR Technology (CEHRT) use by all providers and suppliers designated as eligible clinicians (ECs) under the MACRA NPRM who are participating in the ACO. This measure would be phased into pay for performance after two years as a pay-for-reporting measure. CMS also proposes an alternative reporting requirement for this measure, allowing for pay for reporting in all performance years, to exempt the measure from the minimum attainment level rules, and make these modifications apply only to MSSP tracks that meet the requirements to become Advanced Alternative Payment Models (APMs).

Lastly, CMS proposes to retire and remove various ACO measures to better align with the Core Quality Measures Collaborative core measure set, reducing the total number of measures in the ACO measures set for 2017 from 34 to 31.

NAACOS Key Recommendations:

- **NAACOS thanks CMS for its quality measure alignment efforts, however we urge CMS to make several changes to the agency's quality measure proposals to better reflect ACO clinical care practices.**
- **NAACOS urges CMS not to finalize its proposal to add the new measure, Use of Imaging Studies for Low Back Pain, as it is inappropriate as a measurement for ACOs given their patient population.**
- **NAACOS requests that CMS evaluate the new Ambulatory Sensitive Condition Acute Composite measure as a pay for reporting measure only in all three performance years.**
- **NAACOS opposes CMS's proposal to make changes to the measure specification for ACO Measure 11 to assess the ACO on the degree of Certified EHR Technology (CEHRT) use by all providers and suppliers designated as eligible clinicians (ECs) under the MACRA NPRM who are participating in the ACO. Additionally, due to CMS transitioning from Meaningful Use to the Advancing Care Information requirements starting in 2017, NAACOS also urges CMS to make this measure pay for reporting only in all three performance years.**

Additional Comments: CMS proposes several changes to the ACO quality measure set to better align with the Core Quality Measures Collaborative measure set established for ACOs in March of this year. While we greatly appreciate CMS's efforts to look for ways to better align quality measure reporting in the public and private sectors, we have concerns with several of the proposals made by CMS. Specifically, we oppose CMS's proposal to add ACO measure 44 (Use of Imaging Studies for Low Back Pain) to the MSSP ACO measure set. The use of this measure for the MSSP population is inappropriate and will result in small sample sizes, as CMS points out in the proposed regulation. While aligning quality measure reporting is a priority for NAACOS and our members, CMS must also recognize that not all measures applicable in the private setting will be appropriate for use in certain CMS programs such as the MSSP. Since this measure applies to those patients ages 18 to 50 years of age resulting in a small sample size for the MSSP population, the addition of this measure would be inappropriate and divert ACO resources away from focusing on more widely applicable and meaningful measures. Should CMS finalize this proposal, at a minimum the measure must remain pay-for-reporting only in

all three performance years so ACOs' quality scores and ultimately shared savings are not affected by this flawed measure.

CMS also proposes to add ACO measure 43 (Ambulatory Sensitive Condition Acute Composite) to the ACO measure set, phasing the measure into pay for performance after two years as a pay-for-reporting measure. The addition of this measure while removing more chronic condition-focused measures will require a fundamentally different approach in shifting focus to acute conditions such as dehydration, bacterial pneumonia and urinary tract infection. This change will take significant time for ACOs to operationalize, and therefore we urge CMS to evaluate the new Ambulatory Sensitive Condition Acute Composite measure as a pay-for-reporting measure only in all three performance years.

Additionally, CMS proposes to replace ACO measure 39 (Documentation of Current Medications in the Medical Record) with the previously used ACO measure 12 (Medication Reconciliation) in the Care Coordination/Patient Safety domain. We urge CMS to clarify which Medication Reconciliation measure would be utilized should the proposal be finalized, as the National Quality Forum (NQF) currently lists two Medication Reconciliation measures.

Lastly, CMS proposes to make changes to the specifications of ACO Measure 11 (Percent of Primary Care Physicians Who Successfully Meet Meaningful Use Requirements) to assess the ACO on the degree of CEHRT use by all providers and suppliers designated as ECs under the MACRA NPRM who are participating in the ACO. We oppose these proposed changes. NAACOS believes ACO Measure 11 as it currently exists is sufficient to meet the criteria an APM must possess to be considered and Advanced APM under the recent MACRA and QPP proposals. In the MACRA NPRM, CMS proposes to allow the Shared Savings Program to meet the criterion for Advanced APM use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use, such as the percentage of ECs that use CEHRT. An ACO's patient attribution is based on primary care providers' services, therefore evaluating the percent of primary care providers using CEHRT in the ACO is sufficient to meet the Advanced APM EHR use standard proposed by CMS. ACOs need stability in the measure set, particularly as they transition to new requirements under the Advancing Care Information performance standards included in the MACRA NPRM proposals. These proposals establishing MIPS would make significant changes to the current EHR reporting requirements under Meaningful Use. These changes will take substantial time and effort to operationalize. Therefore, we also urge CMS to make ACO Measure 11 pay for reporting only for all three performance years to provide ACOs with sufficient time to transition to the new Advancing Care Information reporting requirements. Should CMS finalize their proposal to modify the measure specification to assess the ACO on all clinicians' performance under Advancing Care Information requirements, those ECs who are excluded from the Advancing Care Information requirements under MIPS must also be excluded from the denominator of ACO Measure 11.

CMS Proposal: Changes to Validation Process for ACOs Submitting Quality Measures
CMS proposes several changes to the current validation process for ACOs submitting quality measures, including increasing the number of records audited per measure to increase the level of confidence that the true audit match rate is within five percentage points of the calculated result. CMS would also conduct the quality validation audit in a single step going forward, rather than the current multi-phased process. CMS would not provide an opportunity for ACOs to correct and resubmit data for any measure with a greater than 10 percent mismatch and instead would calculate an overall audit match rate. The overall match rate would be derived by dividing the total number of audited records that match the information reported in the Web Interface by the total number of records audited. If an ACO fails an audit, under these proposals the ACO's overall quality score would be adjusted in proportion to its audit performance. The audit-adjusted quality score will be calculated by multiplying the ACO's overall quality score by the ACO's audit match rate. Lastly, CMS also proposes that any ACO with an audit match rate of less than 90 percent may be required to submit a corrective action plan (CAP).

NAACOS Key Recommendations:

- **NAACOS opposes the proposed changes to the current quality measures validation audit process. We urge CMS to maintain the current process going forward.**
- **Should CMS finalize these proposals, a process to appeal the adjusted overall quality score should be provided.**

Additional Comments: NAACOS has deep concerns with CMS's 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. Often times when ACOs are audited under the current process and are found to have a greater than 10 percent mismatch in what was reported versus what was included in the medical records, it is a result of a misreading of the measure specifications and/or a training issue that can easily be remedied with education. The proposed new auditing method instead indicates fraud has taken place and removes the learning opportunities that currently exist for ACOs to be educated through the audit and change their processes to remedy the errors. Instead, we urge CMS to maintain the current measure validation process for quality reporting. Should CMS finalize these proposals, a process to appeal the adjusted overall quality score must be provided.

CMS Proposal: Alignment with other quality reporting requirements and MACRA Provisions
Due to the fact that the Physician Quality Reporting System (PQRS) and Electronic Health Record (EHR) Incentive Programs are sunsetting in 2018 (based on 2016 reporting), CMS proposes several technical changes to regulatory language to incorporate this change. Starting in 2019, the QPP will take the place of the current PQRS and EHR Incentive Programs. As such, CMS proposes to require ACOs to report all MSSP quality measures through the CMS Web Interface to satisfy reporting requirements for the quality performance category under the MIPS. CMS also proposes that going forward, any changes made to the Web Interface measure set would be made through QPP rulemaking and would be applicable to ACO quality reporting under the MSSP.

NAACOS Key Recommendation:

- **NAACOS supports CMS's proposals to align ACO quality measure reporting with the MIPS quality reporting requirements.**

Additional Comments: As stated in our comments in response to the MACRA NPRM, we support CMS's proposals to align ACO quality measure reporting with the MIPS quality reporting requirements. This will allow ACOs to continue to focus on the Group Practice Reporting Option (GPRO) Web Interface measure they report through the MSSP and Next Generation ACO models, and we support the proposal.

PQRS and Value-Based Payment Modifier Changes

CMS Proposal: To address concerns about Eligible Professionals (EPs) who are unable to avoid PQRS penalties if their ACO fails to successfully report PQRS on their behalf, CMS proposes to allow affected EPs that participate in an ACO to report separately for the 2017 PQRS payment adjustment. CMS proposes a secondary reporting period of January 1 through December 31, 2016 to avoid the 2017 PQRS penalty, and this reporting period would also coincide with the reporting period for the 2018 PQRS penalty. Individual clinicians and groups would be able to report using the registry, Qualified Clinical Data Registry (QCDR), or EHR reporting options. The Value-Based Payment Modifier (VM) affects MSSP ACOs as of the 2015 reporting year, which corresponds to the 2017 payment adjustment year. Therefore, CMS similarly proposes to allow solo practitioners to report individually or allow groups to report PQRS as a group outside of the ACO to avoid 2017/2018 VM penalties, based on the same reporting period in 2016.

CMS also proposes changes to the informal VM review process to offer protection to providers without necessitating CMS recalculate all bonuses and penalties across the VM, which is a budget-neutral program.

Specifically, CMS proposes that in cases where there is a widespread claims data issue or a systematic issue with quality data submitted for PQRS that renders it unusable for calculating a TIN's composite scores for quality (or cost for non-ACOs), CMS would classify the TIN's quality (or cost for non-ACOs) composite as "average." Further, when errors are discovered for a TIN's payment calculation, CMS proposes to reclassify EPs as "average quality" when originally classified as "low quality," as "average cost" when originally classified as "high cost," and would allow EPs to retain their original classification when classified as "high quality," "average quality," "low cost" or "average cost."

NAACOS Key Recommendations:

- **NAACOS thanks CMS for its efforts to provide flexibility to clinicians who may be penalized in PQRS and the VM should the ACO fail to successfully report quality measures on their behalf.**
- **NAACOS supports CMS expanding VM informal review opportunities and mitigating the negative effects of widespread claims data or systematic issues on VM scores.**

Additional Comments: NAACOS appreciates CMS's efforts to provide clinicians with the flexibility to report separately from the ACO in cases where the ACO is unable to report this data on their behalf. We support the proposed secondary reporting period of January 1 through December 31, 2016 to avoid 2017 and 2018 PQRS and VM penalties. We encourage CMS to continue providing these types of alternative options for clinicians in future program years when these clinicians will be subject to the MIPS program requirements and corresponding payment adjustments. We also support the proposal to hold harmless the quality and cost scores of providers whose VM performance would be hurt by systematic or widespread claims data issues. As CMS implements more value-based payment programs and models, it is essential the agency protect providers from systematic failures beyond providers' control.

SNF 3-Day Rule Waiver Beneficiary Protections

CMS Proposal: CMS has concerns that in limited circumstances, such as when a beneficiary is no longer enrolled in Medicare Part B, the beneficiary may be held financially liable for non-covered Part A SNF services related to use of the ACO 3-day SNF waiver. To protect beneficiaries, CMS proposes to modify the waiver to include a 90-day grace period that would permit payment for SNF services provided to beneficiaries who were initially on the ACO's prospective assignment list for a performance year but were subsequently excluded during the performance year. CMS would make payments for SNF services furnished to such a beneficiary under the terms of the SNF 3-day rule waiver, provided certain conditions were met. Should a SNF affiliate that is approved for the ACO 3-day rule waiver admit a beneficiary who was never prospectively assigned (and thus ineligible for the waiver) and the claim is rejected only for lack of a qualifying 3-day inpatient hospital stay, CMS proposes that it would not pay the SNF affiliate for those services. In addition, the SNF may not charge the beneficiary, and the ACO may be required to submit a corrective action plan (CAP) to ensure that the SNF 3-day rule waiver is not misused in the future.

NAACOS Key Recommendations:

- **NAACOS supports the proposed 90-day grace period to protect beneficiaries from cost-sharing for the 3-day SNF waiver related to eligibility changes and communication delays.**
- **NAACOS urges CMS to limit instances where an ACO must enter into a corrective action plan based on the actions of its SNF affiliate.**

Additional comments:

We support the waiver allowing beneficiaries to receive SNF care without having the required 3-day inpatient stay. This waiver is currently available for Pioneer and Next Generation ACOs and will be available to MSSP Track 3 ACOs beginning in 2017. The Pioneer and Next Generation model already has a

similar 90-day grace period to address instances where it is not operationally feasible for CMS to notify the ACO and for the ACO to notify its SNF affiliates, ACO participants, and ACO providers/suppliers immediately of the beneficiary's exclusion. The lag in communication may cause the SNF affiliate to unknowingly admit a beneficiary who no longer qualifies for the waiver. In these instances, beneficiaries would appear to qualify for the waiver but would actually be ineligible and could be held financially liable for these services. We support the proposed grace period and CMS's position that beneficiaries shall not be charged in such situations, and recommend CMS finalize this policy to protect Medicare beneficiaries.

However, we recommend CMS be judicious when requiring an ACO to submit a CAP based on the actions of its SNF affiliates. As the Agency wrote in the Proposed Rule, " … we believe it is reasonable that the ultimate responsibility and liability for a non-covered SNF admission should rest with the admitting SNF affiliate" (p. 46440). This is also consistent with the Next Generation ACO Model, which CMS explains "generally places the financial responsibility on the SNF, where the SNF knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services" (p. 46440). The process of submitting a CAP can be labor-intensive, and after submitting a CAP, an ACO is then monitored and evaluated during and after the CAP process. In situations where fault lies with a SNF and not the ACO with which it is affiliated, we ask CMS to consider the appropriateness of imposing such requirements on ACOs.

MSSP Technical Changes

CMS Proposals: CMS proposes to clarify its policy regarding situations where an ACO in a two-sided risk track chose a non-variable Minimum Savings Rate (MSR)/ Minimum Loss Rate (MLR) at the start of the agreement period but falls below 5,000 assigned beneficiaries at the time of financial reconciliation. In these instances, CMS proposes that the ACO would be eligible for shared savings (or losses) and the MSR/MLR used for financial reconciliation would be the MSR/MLR the ACO selected at the start of the agreement period. If the ACO selected a variable MSR/MLR based on its number of assigned beneficiaries, CMS proposes to also allow the ACO to remain eligible for shared savings/losses and would use the same approach for Track 1 ACOs in this situation, which relies on an expanded sliding scale for the MSR/MLR to match the number of assigned beneficiaries.

CMS also proposes to address confusion from an issue in the agency's June 2015 MSSP final rule by modifying regulatory language to clarify that in instances where an ACO acquires a TIN or there is a merger, the merged/acquired TIN is not required to remain Medicare enrolled after it has been merged or acquired and no longer bills Medicare.

NAACOS key recommendations:

- **NAACOS supports and recommends that CMS finalize its clarification that a two-sided ACO which falls below 5,000 assigned beneficiaries at the time of financial reconciliation would maintain eligibility for shared savings/losses and would keep the MSR/MLR it initially selected.**
- **NAACOS supports and recommends that CMS finalize its proposed clarification that when an ACO acquires or merges with a new TIN, if that TIN is no longer used for Medicare billing it does not have to maintain a separate Medicare enrollment record.**

Additional comments: We appreciate CMS's clarification on these two technical corrections. We support these proposals and recommend they be finalized. ACOs that fall below the 5,000 assigned beneficiary population at the time of financial reconciliation should continue to be eligible for shared savings or

losses. This flexibility recognizes that ACO populations fluctuate and are not within the control of the ACO. Therefore, it is important to protect their continued participation in the program at the time of financial reconciliation. As such, it makes sense to honor the MSR/MLR they select in their participation agreement. If the MSR/MLR varies based on the number of beneficiaries, we recommend that MSR be capped at 3.9 percent.

We also support and recommend that CMS finalize its proposed clarification that when an ACO acquires or merges with a new TIN, if that TIN is no longer used for Medicare it does not have to maintain a separate Medicare enrollment record. Maintaining Medicare enrollment in this instance is unnecessary and creates confusion and administrative work for the TIN and Medicare Administrative Contractors who handle enrollment.

Primary Care Proposals

Payment for New Primary Care Services

CMS Proposals: CMS proposes a number of payment changes and new codes, listed in Table 1 below.

Table 1: Proposed Primary Care Codes

Proposed Codes	Overview of Service
GPPP1 GPPP2 GPPP3	Payment for psychiatric care management through three new G-codes based on the psychiatric Collaborative Care Model
GPPPX	Payment for a new G-code that describes care management for beneficiaries with diagnosed behavioral health conditions
GPPP6	Payment for a G-code that provides cognition and functional assessment and development of a care plan for beneficiaries with cognitive impairment
GDDD1	Payment for an add-on G-code for additional services furnished in conjunction with E/M services to beneficiaries with mobility-related disabilities
99358, 99359	Payment for CPT codes for non-face-to-face Prolonged E/M services that are currently bundled and increase payment for face-to-face Prolonged E/M services

CMS proposes to amend its regulations to allow general supervision for the non-face-to-face portion of designated care management services. CMS also proposes to allow general supervision for Chronic Care Management (CCM) and the non-face-to-face portion of Transitional Care Management (TCM) furnished by auxiliary personnel in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

NAACOS key recommendations:

- **NAACOS supports CMS's increased focus on investing in and offering new care coordination services, and we urge CMS to finalize these new codes.**
- **NAACOS supports CMS's proposed flexibility related to general supervision for non-face-to-face services and recommends this be finalized.**

Additional comments: We appreciate CMS's effort to better serve beneficiaries with multiple chronic conditions and the providers who furnish their care by proposing these payment changes and new codes. We urge CMS to finalize the codes listed in Table 1 for Medicare payment beginning in 2017. To ensure

use of these services, we strongly recommend CMS limit administrative requirements necessary to bill for these services. While CMS notes that many of these are G-codes since related CPT codes have not yet been finalized, we recommend CMS consider CPT codes for these services once they are available. 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.

We also support CMS's proposal to allow general supervision, rather than direct supervision, for the non-face-to-face portion of designated care management services. This proposal would apply to the non-face-to-face portion of new codes proposed by CMS now and in the future, thus allowing CMS greater flexibility to permit general supervision. The agency similarly proposes to allow general supervision for CCM and the non-face-to-face portion of TCM furnished by auxiliary personnel in RHCs and FQHCs. General supervision is currently allowed for CCM and the non-face-to-face portion of TCM services billed under the Medicare PFS and this proposal would permit similar flexibility for these services when furnished in RHCs or FQHCs. We recommend CMS finalize these proposals related to permitting general supervision for the non-face-to-face portion of designated care management services.

Chronic Care Management (CCM)

CMS Proposal: CMS proposes several changes related to Medicare CCM, including payment for complex CCM CPT codes 99487 and 99489, effective in 2017, and changes to the CCM scope of service elements. Specific proposed scope of service changes include: an add-on code (GPPP7) related to additional work during the initiating visit, fewer requirements for when the initiating visit is necessary, flexibility for providers to meet 24/7 access requirements to address urgent patient needs and more options to meet requirements related to continuity of care documents (i.e., clinical summaries) used in relation to care transitions. CMS also proposes increased flexibility related to beneficiary consent, including removing the requirement for written beneficiary consent and allowing consent to be given verbally and documented in the medical record.

NAACOS key recommendations:

- **NAACOS strongly supports adding complex CCM CPT codes 99487 and 99489 to Medicare beginning in 2017 and recommends CMS use the same modified scope of service requirements the agency proposes for CCM CPT code 99490.**
- **NAACOS urges CMS to finalize many of the agency's proposed changes to the CCM scope of service elements, which will lessen the provider burden to furnish and bill for CCM services.**
- **NAACOS urges CMS to further modify scope of service elements related to the initiating visit to obtain beneficiary consent and the requirement for use of an EHR meeting specific certification criteria.**

Additional comments: The CCM service is a step in the right direction for providing high quality, coordinated care for Medicare beneficiaries and for preventing adverse events, such as unnecessary hospital readmissions. Having Medicare recognize and reimburse for these services allows ACOs and practices to continue to enhance their focus on care coordination. We strongly urge CMS to finalize introduction of complex CCM codes for use in Medicare, effective in 2017. Unfortunately, as CMS notes in the proposed rule, CCM has been underutilized in Medicare since code 99490 became effective for Medicare in 2015. The onerous scope of service elements required in order to bill for this services have been a significant deterrent for providing this service. **We urge CMS to finalize their proposals to revise**

or remove a number of requirements for CCM to allow more ACOs to provide them to Medicare beneficiaries. Specifically, we support the following changes and urge CMS to finalize these proposals to:

- Modify the 24/7 access to care requirement by removing the need for the care plan to be available remotely to individuals providing CCM services after hours.
- Change the CCM service element to require timely electronic sharing of care plan information within and outside the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.
- No longer require a beneficiary's written consent (including authorization for the electronic communication of medical information with other treating providers) along with documentation of the discussion in the patient's medical record. Allowing this consent to be given verbally and documented in the medical record is sufficient and would eliminate an administrative hurdle for those providing CCM.
- No longer require the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits and to document beneficiary consent.
- Remove the requirement to document the provision of a care plan to a beneficiary using certified EHR technology and to allow a care plan to be given in electronic or written format to a beneficiary and/or a caregiver, as appropriate.
- In relation to care transitions, remove the requirement for standardized content for clinical summaries created/formatted according to certified EHR technology and required to be transmitted electronically. The current requirements prohibit fax, except for in extenuating circumstances, but CMS would allow fax as an acceptable method to exchange/transmit clinical summaries (now referred to as continuity of care documents).

In addition to finalizing the proposals above, we request CMS take the following actions to ensure ample use of CCM:

- Finalize proposals giving more flexibility to obtaining beneficiary consent but remove the requirement that obtaining consent must be initiated as part of a face-to-face visit, including an Annual Wellness Visit, *Initial Preventive Physical Examination* (*IPPE) or face-to-face Evaluation & Management (E/M) visit*. *While CMS proposes to remove the required initiating visit for patients who have been seen in the last year, we urge the agency to remove this requirement for all patients.* The conversation initiating CCM and discussing beneficiary consent could easily be done over the phone where a care coordinator would walk the patient through the beneficiary consent form, after which the patient could either mail a signed copy of the form, or log into an online patient portal to provide their consent. Ultimately, there could be a variety of ways in which an ACO or practice could adequately explain the service and discuss beneficiary consent. CMS should provide flexibility to those who may have creative ideas for how to engage patients and begin furnishing CCM. **Consequently, we urge CMS to remove the face-to-face requirement for obtaining beneficiary consent.**
- Remove the requirement that CCM services be furnished using, at a minimum, the edition(s) of certification criteria acceptable for the EHR Incentive (meaningful use) Program as of December 31 of the calendar year preceding each CCM payment year. (For the CY 2017 PFS payment year, this would mean technology meeting the 2014 edition of certification criteria). 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 this service, 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.**

We support CMS finalizing, as proposed, that the revised scope of service elements would apply to all CCM services, including those for complex chronic care management and those furnished by RHCs and FQHCs.

Expansion of the National Diabetes Prevention Program and Reimbursement for Diabetes Self-Management Training

CMS proposal: Effective in 2018, CMS proposes to reimburse for diabetes prevention program (DPP) training for pre-diabetic patients and classify the DPP as an additional preventive service under Medicare Part B. The proposed curriculum is approved by the Centers for Disease Control and Prevention (CDC) and includes 16 core sessions, 6-month follow-up and potential for another year of follow-up for those graduates maintaining a minimum level of weight loss. If finalized, payment will be tied to the number of sessions attended and a minimum of 5 percent of weight loss.

CMS also seeks feedback on the appropriateness of the current payment and intensity of services for Diabetes Self-Management Training.

NAACOS Key Recommendations:

- **NAACOS supports expanding the DPP in an effort to enhance beneficiary care and outcomes related to pre-diabetes and requests clarification on CMS's intent for who would participate in an expanded DPP.**
- **NAACOS urges CMS to align pre-diabetes education codes and billing requirements with established Medicare diabetes self-management education and training services and increase reimbursement for these services.**

Additional comments: We strongly support structured health behavior change programs such as the DPP which are designed to manage and prevent high cost, chronic conditions such as diabetes. Many ACOs refer patients to DPPs in their community and would continue to do so should the program be expanded. We support CMS's expansion of the DPP but request clarification on whether and how existing Medicare providers would participate. Based on CMS's proposal, it is unclear if the DPP would be expanded in a manner which would only be appropriate for non-physician community-based organizations like the Young Men's Christian Association (YMCA), which received a CMS Health Care Innovation Award to lead local DPPs in eight states, or if CMS intends for Medicare entities, such as ACOs or physician group practices, to participate directly in this program. This distinction is very important and we ask CMS to clarify this in order for us to properly comment prior to expansion in 2018.

Should the program be expanded with the goal of participation by existing Medicare providers, there are a number of issues to consider. For example, Medicare entities including ACOs are thoroughly vetted by CMS via their ACO application process, and the individual group practices, hospitals and clinicians of which an ACO is comprised 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 CDC certification process as a community-based organization that does not traditionally deal with Medicare. Further, the DPP 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. Directly providing the DPP would not be cost effective for many ACOs under the current reimbursement, and we

recommend increased payment for this program. 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. **In addition to a modified and expanded DPP applicable to Medicare providers, we urge CMS to align pre-diabetes education codes and billing requirements with established Medicare diabetes self-management education and training services and increase reimbursement for these services.**

Other Medicare Proposals

Collecting Data on Resources Used in Furnishing Global Services

CMS proposal: MACRA requires CMS to develop a process to gather information needed to value global surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017 to improve the accuracy of valuation of surgery services beginning in 2019. Beginning in 2017, CMS proposes to require all practitioners furnishing 10- and 90-day global services to report newly proposed G-codes on claims to identify details such as the number and level of pre- and post-operative visits furnished for these services. CMS does not propose, at this time, to financially penalize providers for failing to report this information but the agency states it may consider withholding up to 5 percent of payments for these services in the future if compliance is low.

CMS also proposes to conduct a survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks. The agency proposes a separate but similar survey specifically for ACOs, which would begin with an initial phase of primary data collection using a range of methodologies in a small number of ACOs (Pioneer and Next Generation ACOs), followed by development, piloting, and validation of an additional survey module specific to ACOs. If finalized, a survey of practitioners participating in approximately four to six ACOs using the survey instrument along with the additional ACO-specific module will be used to collect data on pre- and post-operative visits.

NAACOS key recommendations:

- **NAACOS urges CMS to limit the administrative burdens associated with a global surgical services data collection effort by using a sample of providers.**
- **NAACOS recommends that CMS use an appropriate sample of Medicare ACOs for the global surgical services data collection effort.**

Additional comments: We recognize that CMS is required by statute to collect information related to 10- and 90-day global surgical services, beginning in 2017 with related payment adjustments starting in 2019. However, CMS's proposed data collection effort is incredibly large in scope, and we note that the agency is not required to collect data from all providers. We urge CMS to limit this effort by selecting a sample of providers from which to collect this information, thus reducing burdens across the industry. We also urge the agency to invest the necessary resources in educating providers on this initiative rather than use penalties to force compliance.

CMS proposes a specific survey for ACOs and notes its initial data collection effort would focus on Next Generation and Pioneer ACOs. The ACO cohorts for both of these programs are very small, and the Pioneer ACO program would end before the start of this data collection effort in 2017, making this reference confusing. We urge CMS to gather preliminary data from ACOs in the MSSP and Next

Generation model to ensure an adequate reflection of Medicare ACOs. While we strongly encourage CMS to limit administrative burdens for ACOs related to this survey, we also request the agency ensure an adequate sample size reflective of the Medicare ACO population. As such, we recommend a sample of approximately 10 percent of Medicare ACOs.

Conclusion

We support many of the proposals in the 2017 proposed 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 and proposals presented from the ACO community outlined in this letter. Thank you for your consideration of our comments.

Sincerely,

Clif Gaus
President and CEO