August 12, 2019

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-6082-NC) Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork

Dear Administrator Verma:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the Request for Information; Reducing Administrative Burdens to Put Patients First, published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on June 11, 2019.

NAACOS is the largest association of accountable care organizations (ACOs), representing more than 6 million beneficiary lives through more than 330 Medicare Shared Savings Program (MSSP), the Next Generation ACO Model, and commercial ACOs. NAACOS is an ACO member-led and member-owned nonprofit that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health, patient outcomes, and healthcare 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.

Reducing regulatory burdens is critical to ACOs' success and we appreciate the opportunity to provide this input to CMS. We also thank CMS for implementing several issues NAACOS raised in our last letter in response to this initiative. These changes have resulted in reduced regulatory burden, allowing for more time to devote to care transformation efforts. We have identified additional or remaining issues for your attention, included below. To summarize, our key points include the following requests:

High Priority Items

- Remove new beneficiary notification requirements
- Exclude all ACO patients from bundled payment programs and demonstrations
- Permit ACOs to have additional time to remain in shared savings-only models
- Provide adequate shared savings rates for ACOs and apply the following shared savings rates: 50 percent for Basic Levels A and B, 55 percent for Basic Levels C and D, and 60 percent for Basic Level E

- Remove the arbitrary distinction of high and low revenue ACOs and to apply low revenue policies across all ACOs
- Provide ACOs access to valuable and actionable real-time data needed for successful care coordination
- Prohibit the late notification of quality measure specification changes
  Align Quality Payment Program (QPP) Advanced Alternative Payment Model (APM) numerator and denominator calculations with those used for specific APMs, such as MSSP and the Next Generation ACO Model
- Modify the current risk adjustment policy use a more appropriate range of +/- 5 percent, cap the risk ratios in aggregate across the four beneficiary enrollment types, study risk adjustment across Medicare programs, and identify and implement the most appropriate approach consistently across all Medicare programs
- Modify benchmark methodology to remove ACO beneficiaries from the population used to determine regional expenditures
- Expand the use of payment rule waivers
- Permit individual ACOs to appeal a payment determination if they feel the calculation was made in error
- Provide full transparency for how CMS calculates ACO program methodologies
- Give ACOs additional flexibility under the physician self-referral law for ACOs
- Provide new opportunities for ACOs to increase beneficiary engagement through incentives for choosing high-quality, efficient providers that work collaboratively with the ACO
- Allow indefinite participation in Basic Level E and make the Enhanced Track voluntary

Medium Priority Items

- Provide more transparency to ACOs regarding Merit-Based Incentive Payment System (MIPS) scores and provide ACOs with the opportunity to appeal scores when appropriate
- Provide more transparency to ACOs regarding MIPS scores and provide ACOs with the opportunity to appeal scores when appropriate
- Modify the process to classify ACO beneficiaries with end stage renal disease (ESRD) for ACO benchmarks
- Allow ACOs direct access to CMS program integrity to report suspected fraud and abuse
- Reduce regulatory burdens to the greatest extent possible for ACOs also evaluated under MIPS
- Revise MSSP Data Use agreement (DUA) requirements by removing the approval process to add a party to a DUA
- Remove the requirement for tail period coverage and lower the repayment mechanism amounts for Basic Track Levels C, D, and E. NAACOS requests that CMS provide new repayment mechanisms, including reinstating reinsurance and introducing an option for a future withhold of Medicare payments
- Simplify ACO marketing requirements by removing the requirement to submit internal provider-facing materials to CMS
- Offer Provider Enrollment, Chain and Operating System (PECOS) view-only access to ACOs to see information on Tax Identification Number (TIN)/National Provider Identifier (NPI) data for ACO participants

High Priority Items:

Beneficiary Notification Requirements

Key comment: NAACOS urges CMS to remove new beneficiary notification requirements.

Comments: In the Pathways to Success final rule, CMS modified the current beneficiary notification requirements. Beginning July 1, 2019, CMS requires a standard written notification be provided annually to each Medicare fee-for-service (FFS) beneficiary either prior to or at their first primary care visit of the performance year. CMS issued ACOs a template letter to provide to patients only one business day prior to the effective date of the new requirement. This has resulted in confusion among ACOs regarding which patients must receive the notification, how the notification may be disseminated, and what, if any language may be altered in the notification. To date, CMS has provided no additional guidance on this new requirement.

We urge CMS to issue detailed guidance to ACOs regarding which patients must receive the notification, as some ACO coordinators have communicated to ACOs that all FFS patients must receive the notifications, while others said that only assigned MSSP patients must receive the notifications. CMS must also provide additional guidance on which methods of distribution are acceptable for the beneficiary notification, including how an ACO must document confirmation of receipt of the notification. It is critical that CMS communicate these facts in a transparent and consistent manner to avoid confusion among ACOs as well as the patients they serve. To date, some information has been shared sporadically and inconsistently through ACO coordinators assigned to ACOs, resulting in mass confusion on this topic.

Additionally, we urge CMS to remove this beneficiary notification requirement going forward. When this requirement was first in place at the inception of the MSSP, ACOs reported patient confusion, which resulted many times in beneficiaries opting out of data sharing, thereby reducing the ACO's ability to appropriately care for the patient and work to better coordinate the patient's clinical care. As written, we fear the new notification language will have the same effect and request CMS remove this requirement. Instead, allow ACOs to communicate with their patients directly regarding the work of the ACO in terms that make the most sense for the ACO, the practice, and the patient.

Should CMS maintain this requirement, the standard template notification language must be altered. The template notification language shared with ACOs appears to be very similar to the original beneficiary notification language. CMS noted in the final Pathways to Success rule that they would be engaging partners and ACOs to conduct beneficiary focus groups to ensure the content of the template notice is written in plain language and easy for beneficiaries to understand. NAACOS has not heard from CMS or ACOs who have been contacted by CMS for this purpose. We urge CMS to conduct focus groups and engage in meaningful conversations with stakeholders to draft beneficiary notification language that is not confusing or misleading to patients.

Program Overlap Issues

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

Comments: The CMS Innovation Center 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 population health models like ACOs and other CMS and Innovation Center programs, which lead to negative unintended consequences that undermine ACOs by excluding all ACO patients from other payment models. NAACOS was pleased to see CMS make small steps toward solving this problem when they gave attribution

precedence to Track 3 and Next Generation ACO patients. However, the Innovation Center and CMS have recently released a policy for the Bundled Payments for Care Improvement Advanced (BPCI-A) program which, starting in Program Year Three, will give precedence to bundlers over all MSSP ACOs, assigning patients first to a bundled payment episode while still holding the ACO accountable for that patient's costs of care. It is imperative that CMS and the Innovation Center 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.

Maximum Time Permitted in Risk-Based Models

Key comment: NAACOS urges CMS to permit ACOs to have additional time to remain in shared savings-only models.

Comments: In the Pathways to Success final rule, CMS allowed ACOs only two years in shared savings-only models before requiring a move to risk-based models. NAACOS continues to have significant concerns that reducing the amount of time available in shared savings-only models would be detrimental to the program and the administration's goals of encouraging providers to participate in APMs. Analysis shows that ACOs improve over time in the program. ACOs participating in the MSSP over a longer period of time show greater improvement in financial performance, demonstrating the value of such models and the need to allow ACOs sufficient time to demonstrate positive results. For example, as detailed in Tables 1 through 3 below, it took the average ACO that earned savings in 2017 three years to initially generate savings. Of the 142 ACOs that earned shared savings payments in 2017 and had prior program experience, 36 percent had losses (i.e., expenditures higher than benchmarks) in one of their first two years of the program. Had CMS's new policies been in place at that time, these ACOs would not have had the opportunity to continue in the program and go on to demonstrate success. A critical component of performance improvement lies in the ACO's ability to analyze the performance data being provided to the ACO and make targeted improvements based on this information. Under CMS's current policy, new ACOs will have only one year of performance data before being required to move to a risk-based model. This is not sufficient and will not allow ACOs the opportunity to make strategic decisions regarding performance improvement, which allow them to demonstrate success in future program years.

Table 1: Net Savings by ACO Cohort

MSSP Cohort (based on start year)	Net Savings to Medicare, 2017* (millions)	Average Savings per Beneficiary
2012	$87	$257
2013	$118	$184
2014	$172	$135
2015	$5	$124
2016	-$34	$105
2017	-$34	$44
Total	$314	---

*Net savings factors in bonuses paid to ACOs

Table 2: Share of ACOs with Shared Savings by Start Date and Performance Year

Start Year	N	PY13	PY14	PY15	PY16	PY17
2012	63	32%	37%	42%	42%	51%
2013	62	21%	27%	37%	36%	44%
2014	79	NA	19%	22%	36%	43%
2015	76	NA	NA	21%	26%	28%
2016	96	NA	NA	NA	18%	29%
2017	96	NA	NA	NA	NA	21%

Table 3: Savings Patterns among ACOs with Five Years of Participation

Savings Patterns	Number	Percent
No savings	57	15%
4 years of losses then savings	53	14%
3 years of losses then savings	87	23%
2 years of losses then savings	55	15%
1 years of losses then savings	55	15%
5 years of savings	39	10%
Other patterns	30	8%

Research also shows that ACOs in shared savings-only models save CMS money and improve quality for the patients they serve. MSSP performance year 2017 results show net savings to the Medicare Trust Fund of $314 million after accounting for shared savings payments made to ACOs. Further, as noted in the June 2018 Medicare Payment Advisory Commission (MedPAC) report, Chapter 8, *Medicare Accountable Care Organization Models: Recent Performance and Long-term Issues*, there are a number of scientific evaluations that show ACO savings. In another example, a peer-reviewed study by Harvard University researchers found that the MSSP saved more than $200 million in 2013 and 2014 and $144.6 million in 2015 after accounting for shared savings payments earned by ACOs. A study by Dobson DaVanzo & Associates using similar methods that compare ACO spending to what Medicare spending would be like in the absence of ACOs found that ACOs saved $2.7 billion from 2013 through 2016 and reduced Medicare spending by more than $660 million after accounting for shared savings payments. Even CMS's own impact analysis included in the Pathways to Success rule estimates that the overall impact of ACOs, including "spillover effects" on Medicare spending outside of the ACO program, lowered spending by $1.8 – $4.2 billion (0.5 – 1.2 percent) in 2016 alone.

These, which analyze MSSP at a time when the majority of ACOs were shared savings-only, analyses provide important evidence that ACOs save more money for Medicare than what is reflected in basic evaluations of performance compared to CMS benchmarks. Additionally, ACOs have also demonstrated impressive quality results, as demonstrated in a 2017 Health and Human Services Department Inspector General (OIG) report, *Medicare Program Shared Savings ACOs Have Shown Potential for Reducing Spending and Improving Quality*. This report found that ACOs achieved high quality and in particular noted progress on important measures including reduced hospital readmissions and screening beneficiaries for risk of falling and depression. Evidence clearly shows that ACOs improve over time in the program and that shared savings-only models generate savings to CMS and improve quality of care for the patients they serve. Therefore, it is critical that CMS allow ACOs to remain in shared savings-only models (Basic Track Levels A and B) for more than two years.

Specifically, NAACOS urges CMS to allow all new ACOs to remain in Basic Track Level A for two years and Basic Track Level B for an additional two years before requiring the ACO to move to Level C in the fifth and final year of their agreement. These ACOs should then be permitted to begin their second agreement period at Basic Track Level D where they would participate for three years and progress to Level E for the final two years of their second agreement period (with options to progress more quickly if the ACO chooses). Providing ACOs with four years in shared savings-only models provides the ACO with only two to three years of performance data, the minimum that would be necessary to identify trends and opportunities for transformation and improvement. It is critical that CMS provide ACOs with additional time in shared savings-only models to allow for a successful transition from fee-for-service to value-based care.

Shared Savings Rates

Key comment: NAACOS urges CMS to provide adequate shared savings rates for ACOs and apply the following shared savings rates: 50 percent for Basic Levels A and B, 55 percent for Basic Levels C and D, and 60 percent for Basic Level E.

Comments: The reduction in shared savings rates finalized in the Pathways to Success rule provides a disincentive for new ACOs to enter the program, threatening the long-term future of the MSSP. Many existing ACOs expressed concern about these reductions and stated they would not have entered the program with inadequate shared savings rates of below 50 percent. As noted in a comment letter from researchers at Harvard to CMS in response to the Pathways proposed rule, "shared savings rates have been low in the MSSP, allowing ACOs in Track 1 to keep no more than 50 percent of the difference between its expenditures and its benchmark. Because imperfect quality scores reduce the shared savings rate, it has been even lower, averaging 44.2 percent in 2014 and 47.8 percent in 2017." NAACOS' members report spending almost $2 million a year on average for MSSP participation, including investments made in health information technology, population health management, and ACO administration. Inadequate shared savings rates do not allow ACOs to recoup those investments and deter participation.

The shared savings rates have been debated numerous times with many calls to increase shared savings rates above 50 percent. For example, many commenters including MedPAC have called for much higher shared savings rates, such as 75 percent, to incentivize ACO participation. Given repeated calls for CMS to raise shared savings rates, it is very disappointing that the agency cut those rates this past year. There have been public comments from CMS leaders that ACOs in shared savings-only models do not generate savings. However, CMS data on PY 2017 MSSP results, available in this Public Use File, shows this claim is not true. ACOs in shared savings-only models and those with downside financial risk both had net positive savings in 2017. In fact, the savings per beneficiary was higher for ACOs in Track 1. Therefore, NAACOS urges CMS to provide adequate shared savings rates for ACOs and apply the following shared savings rates: 50 percent for Basic Levels A and B, 55 percent for Basic Levels C and D, and 60 percent for Basic Level E.

High Revenue and Low Revenue ACO Designations

Key comment: NAACOS urges to remove the arbitrary distinction of high and low revenue ACOs and to apply low revenue policies across all ACOs.

Comments: In the final Pathways to Success rule, CMS created a new distinction that measures Parts A and B FFS revenue compared to ACO benchmarks in order to categorize ACOs as "high revenue" or "low revenue" ACOs. This distinction determines program specifics such as the timing for when an ACO must move to risk. For example, new high revenue ACOs are required to move to the Enhanced Track after one agreement period in the Basic Track. In the rule, CMS stated its belief that ACOs whose participants have greater total Medicare Parts A and B FFS revenue relative to their benchmarks have more ability to control costs and may be better financially prepared to move to greater levels of risk. We do not support dividing ACOs into these arbitrary categories and applying different schedules for how and when they must progress along the risk continuum. The 35 percent threshold for making the determination is arbitrary and creates division and program complexity where none should exist.

Being "high" or "low" revenue does not determine when an ACO is ready for risk or how much risk they are able to assume. Regardless of structure, significant investments are needed in population health platforms and care process changes for ACOs to bear risk. The financial position and backing of a particular ACO as well as the ability to assume risk depends on a variety of factors, such as local market dynamics, culture, leadership, financial status, previous program success, and the resources required to address social determinants of health. Providers in rural areas and safety-net providers, which care for some of the most vulnerable patient populations, often face even greater challenges than other providers when considering taking on risk. Research shows that insurers and venture capital funds are investing millions of dollars in

certain ACOs, which are often physician-led. CMS is unable to identify if an ACO is well capitalized through outside sources, such as investors or insurers, and should therefore not use an arbitrary calculation of revenue compared to benchmark to make this assumption.

The challenge of being forced into risk is of great importance to ACOs of all sizes, composition, and ownership. All ACOs should be on the same path to assuming risk, which should include a gradual ramp up of risk, sufficient shared savings rates, and the ability to participate indefinitely in Basic Level E without having to move to the Enhanced Track. We urge CMS to eliminate the high and low revenue distinctions.

In addition to this recommendation, we recommend that CMS support ACOs by reinstating advanced funding opportunities to enable ACOs to start and continue the path to value. The agency previously offered programs that help fund ACOs up front, with those payments later recouped via shared savings. These programs, such as the ACO Investment Model (AIM) or similar ones, should be reinstated to help ACOs fund activities and transformations early on in ACOs' development.

Access to Data

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

Comments: CMS should make Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) feeds available to ACOs and Medicare providers participating in APMs. HETS allows providers to check Medicare beneficiary eligibility in real-time using a secure connection. Anytime a Medicare beneficiary visits a medical provider, including an emergency department, inpatient hospital, or free-standing facilities like imaging centers and ambulatory surgical centers, an ACO could be aware with access to this HETS feed. Such awareness would allow ACOs to communicate with treating providers at the hospital or elsewhere and to work with the beneficiaries to ensure optimal treatment, medication adherence, and follow-up care. At a minimum, CMS could allow ACOs to tap into the system themselves to access the data, a request the agency has denied.

CMS earlier this year proposed sharing electronic notifications for hospital admission, discharges, and transfers (ADTs) a condition of participation, and NAACOS was supportive of the move. But sharing these electronic ADT alerts wouldn't provide the universal notification ACOs need and HETS provides. ACOs' access to critical HETS information in real time would allow ACOs to further enhance care coordination, improve patient outcomes, and reduce costs – all are tenants of advancing value-based payment models. In order to succeed in value-based care and APMs, providers need to know where patients are receiving care in real-time, since there's a significant delay in this knowledge through claims. Our request related to opening HETS feeds would serve several administrative priorities, including increasing data access, improving the utility of health IT systems, and advancing alternative payment models.

NAACOS believes this request is technologically feasible and could be achieved with little burden on the agency. CMS evaluated this recommendation several years ago and determined that because these real-time inquiries do not identify if the patient is being scheduled for an event, for example in a future surgery, there are false positives that ACOs would be confused by. ACOs, on the other hand, say they could manage through other means to identify the likely positives that need action. The HETS staff in previous discussions said they have no funding to modify the system and did not perceive the same value in providing this information. We urge CMS leadership to develop a mechanism to share more robust health data, including that from HETS, with ACOs in real time to ensure patients receive the right care, at the right time, and in the right setting.

Quality Measure Changes

Key Comment: NAACOS urges CMS prohibit the late notification of quality measure specification changes.

Comments: In regard to the 2018 and 2019 performance periods, CMS has notified ACOs of quality measure specification changes close to the end the performance year or in some cases after the performance year has closed and reporting has started. These late notifications result in enormous amounts of time to adjust abstraction and data collection for ACOs. Additionally, when substantial, late notification of measure changes can result in poor performance on the measure due to clinical workflows not being adjusted in advance of the changes to appropriately capture the necessary data for the measure. NAACOS applauds CMS for changing the smoking cessation quality measure, ACO-17, a pay-for-reporting measure in 2018 due to late notification of specification changes, which resulted in inaccurate benchmarks for the measure. While we are pleased CMS has taken action to hold ACOs harmless from performance on this measure, we also urge CMS to solicit stakeholder feedback on proposed changes and provide ample notification of such changes in the future. This notification must be provided in the form of a widespread, clear communication to ACOs about the quality measure specification changes through multiple communications (such as publication in the ACO Spotlight Newsletter, updates in the ACO-MS, etc.). Additionally, when such changes result in substantial changes to the measure, we request CMS revert to pay-for-reporting only status for such measure for two performance years as required in § 425.502(a)(4).

QP Methodology

Key comment: NAACOS urges CMS to align QPP Advanced APM numerator/denominator calculations with those used for specific APMs, such as MSSP and the Next Gen Model.

Comments: To qualify for the Advanced Alternative Payment Model (Advanced APM) bonus under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), an ACO participating in an eligible model (ex. the Next Generation ACO Model or MSSP Tracks 1+, 2, 3, Basic Level E, or Enhanced Track) must meet Qualifying APM Participant (QP) thresholds by having a certain proportion of payments or patients "through" the ACO. QP calculations use "attributed" beneficiaries as the numerator and "attribution-eligible" beneficiaries as the denominator. These numerators and denominators are similar to assignment data provided to ACOs in regular reports from CMS, with "assigned" and "assignable" beneficiaries. Many ACOs would like to use the ACO program data to gauge how they would perform relative to the QP thresholds.

However, there are notable differences between these definitions, including using different primary care codes and different providers to identify the beneficiary populations. The differences between the populations used in the QP calculation (attributed beneficiaries / attribution-eligible beneficiaries) compared to a calculation of ACO assigned/assignable beneficiaries are meaningful enough that ACOs cannot rely on the ACO data to accurately predict what their QP score will be. This is problematic because without this knowledge, ACOs may be reluctant to enter into or remain in an Advanced APM out of concern that they may not meet the QP thresholds. As QP thresholds rise over time, it is essential that ACOs can predict how they may perform relative to the thresholds. In addition to the uncertainty for ACOs, calculating similar but different values for the QPP creates unnecessary work and complexity for CMS. Using the ACO definitions and data for QP calculations would reduce burdens on the agency and providers and allow more predictability for ACOs, thus incentivizing them to move into and stay in Advanced APMs. We urge CMS to implement this change.

Risk Adjustment

Key comment: NAACOS urges the agency to modify the current risk adjustment policy use a more appropriate range of +/- 5 percent and to cap the risk ratios in aggregate across the four beneficiary enrollment types. We urge CMS to study risk adjustment across Medicare programs and identify and implement the most appropriate approach consistently across all Medicare programs.

Comments*:* NAACOS has repeatedly advocated for CMS to permit meaningful increases in beneficiary risk scores over time. We appreciated efforts through the Pathways to Success rule to simplify risk adjustment by eliminating distinctions between newly and continuously assigned beneficiaries and allowing minimal risk score changes of up to positive 3 percent over five-year agreements. However, it is important to note that the three percent cap currently in place is applied across a five-year agreement period and is not a year-over-year increase. The selection of 3 percent was arbitrary, and that amount is insufficient when applied across a five-year agreement. For example, for an ACO that started in July 2019, the most that the risk score used in the updated benchmark calculation can change in performance year six (2024) is up to 103 percent of the 2018 risk score (based on 2017 Hierarchal Condition Category (HCC) coding practices). NAACOS urges the agency to modify the current risk adjustment policy use a more appropriate range of +/- 5 percent and to cap the risk ratios in aggregate across the four beneficiary enrollment types.

In order to reduce benchmark volatility, the risk adjustment model version should be consistent between the baseline and performance years. For example, the version 23 CMS-HCC model could be used when comparing risk scores in the 2016-2018 baseline period to those in the 2019 – 2024 performance period. The Next Generation ACO Model follows this convention, demonstrating that it is administratively feasible to maintain a consistent risk adjustment model version throughout the baseline and performance periods.

Accurate risk adjustment should remove or minimize differences in health and other risk factors that impact performance but are outside the ACO's control. While there are many different approaches to risk adjustment, it is unclear why Medicare uses an array of risk adjustment methodologies across its programs. The same risk adjustment approach should be used across Medicare, creating parity and simplicity and emphasizing the need for consensus on the most appropriate methodology. This would also minimize burdens on providers who need to learn many different risk adjustment policies across programs. We urge CMS to study risk adjustment across Medicare programs and identify and implement the most appropriate approach consistently across all Medicare programs.

Benchmark Methodology

Key comment: NAACOS urges CMS to modify MSSP benchmarking policies to address methodological flaws, including removing ACO beneficiaries from the population used to determine regional expenditures.

Comments: 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 shift ACO benchmarks to be less focused just on historical expenditures and to incorporate a growing component of regional expenditures. However, there remain a number of flaws with the benchmarking methodology. One of notable concern is the policy by which CMS calculates expenditures for the purpose of determining the regional component of the benchmark. NAACOS and others have repeatedly raised this concern with CMS, including in our comment letter in response to the 2016 MSSP benchmarking rule, and our concerns remain the same.

Rather than comparing ACOs to themselves and other ACOs, CMS should compare ACO performance relative to FFS Medicare by defining the regional population as assignable beneficiaries without ACO-assigned beneficiaries for all ACOs in the region. In other words, the regional comparator should be FFS patients minus the ACO's patients. This allows for a cleaner comparison between ACOs and FFS and avoids

skewing regional expenditure data by incorporating ACOs' efforts to coordinate care and reduce expenditures. At the very least, CMS should exclude the ACO itself from the region to prevent an otherwise tautological comparison that essentially double counts those ACO-assigned beneficiaries. In an area where the ACO has significant market saturation, it is especially essential to remove the ACO beneficiaries from the regional population to avoid comparing the ACO to itself. CMS could address concerns that removing ACO-assigned beneficiaries may result in an insufficient reference population by increasing the weight of counties with a lower proportion of resident ACO beneficiaries or expanding the regional reference population by adding data from other years or nearby counties.

Additional benchmarking polices that should be addressed include the need to:

- Restore the regional expenditure component to 70 percent (up from the recently revised 50 percent)
- Remove the symmetric +/- 5 percent cap based on national per capita expenditures and allow market forces to address outliers
- Reverse its position on adjusting rebased benchmarks to account for the average per capita amount of savings generated during an ACO's previous agreement period by adding those savings back to the rebased benchmark.
- Adjust the MSSP benchmarking methodology to remove certain expenditures such as those related to MIPS payment adjustments, Comprehensive Primary Care Plus (CPC+) model care management fees and hospital wage index changes.

CMS must make these changes to the methodology to ensure fair and accurate benchmarks.

Payment Rule Waivers

Key comment: NAACOS urges CMS expand the use of payment rule waivers.

Comments: NAACOS appreciated the move by CMS in December's final Pathways to Success rule to extend waivers from the skilled nursing facility (SNF) three-day Rule and permit telehealth use to most risk-based ACOs. While welcomed, NAACOS urges CMS to expand use of these tools to all ACOs. In Medicare's new ACO rules, CMS reduced the number of years that new, shared savings-only ACOs have to move to risk from six years to two years (or three years in certain circumstances). Given this new, expedited timeline, ACOs could be persuaded to enter this voluntary program if they have access to tools like telehealth to best manage patient care and cost before taking on financial risk.

MSSP ACOs are seeking other payment-rule waivers and benefit enchantments that help ACOs and improve patient experience and care. These include waivers to support post-discharge home visits and permit financial incentives for beneficiaries receiving certain primary care services from ACO providers. The latter would ensure care kept within ACOs, while rewarding primary care. We ask CMS to grant all ACOs the ability to waive co-payments for primary care services provided by ACO providers to encourage patients' use of these critical services. Additionally, CMS could waive cost-sharing requirements when treatment, including labs and incidentals, is provided during an Annual Wellness Visit. Currently, providers are required to bill evaluation and management (E/M) services during Wellness Visits, which limits the utility of such patient encounters.

Regarding post-discharge home visits, CMS should waive certain supervision requirements to allow for broader use of these services by ACOs when clinically appropriate. For example, a patient needs follow-up care following an acute hospital stay. They could do well if discharged to the home, if support for a successful transition is in place, but current evidence-based guidelines dictate a brief SNF stay. The post-discharge home visits could be deployed in the first weeks after the hospital stay for medications to be monitored, home transition be safely assessed and resolved, transportation to the physician to be provided, or arrangements for house calls and physical therapy be resolved. The patient may opt to choose

a less restrictive option of post-discharge home visit and return home with the supports provided by the benefit enhancement, rather than the institutional stay in a SNF. 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.

Appeals of Payment Determinations

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

Comments: Current regulation allows for CMS to reopen ACO reconciliation determinations at its own discretion. Yet there is not opportunity for ACOs to appeal a payment determination that may have been made in error. NAACOS urges CMS to offer ACOs that option. 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 later. Furthermore, 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 CMS provide full transparency for ACO program methodologies.

Comments: 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.

Physician Self-Referral Law

Key comment: NAACOS requests CMS provide additional flexibility under the physician self-referral law for ACOs.

Comments: On August 24, 2018, in response to CMS's notice with comment entitled *Medicare Program; Request for Information Regarding the Physician Self-Referral Law [CMS-1720- NC]*, NAACOS detailed its recommendations regarding modifications to the physician self-referral or "Stark Law" that could help support continued growth of the Medicare Shared Savings Program (MSSP) for ACOs. In addition, on October 26, 2018, in response to the OIG's notice entitled *Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP [OIG-0803-N]*, NAACOS outlined specific recommendations related to the application of the anti-kickback statute and beneficiary inducements civil monetary penalties to ACOs participating in the Medicare Shared Savings Program (MSSP). Specifically, NAACOS recommended that OIG and CMS:

- Be mindful of congressional intent to provide unique flexibility for ACOs;
- Codify the MSSP waivers to afford participants certainty and stability;

- Modify the MSSP waivers to clarify that ACOs can extend waiver protection to other models and provide latitude for technical violations;
- Coordinate with other agencies regarding the application of MSSP waivers;
- Maintain the current role of ACO governing bodies in the waiver-approval process; *and*
- Allow in-kind remuneration as a beneficiary incentive for wellness and managing chronic diseases.

We understand that there are several proposals related to this topic pending at the Office of Management and Budget, and we look forward to working with the CMS as it continues its work in this important area.

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.

Comments: Per the Bipartisan Budget Act of 2018 (BBA), CMS launched a Beneficiary Incentive Program (BIP) for risk-based ACOs starting July 1, 2019. The program allows ACOs to provide incentive payments to eligible beneficiaries who receive qualifying services of up to $20 (adjusted annually for inflation) per visit. While we support this proposal, we have concerns with the agency's approach to implementation, which would require the ACO fully fund the costs of such a program. There are numerous upfront costs required to establish and maintain an ACO's operations. ACOs invest these dollars to support the model and efforts to transform patient care, sometimes never realizing these investment costs. Those ACOs that do earn shared savings do not see such funds until years after the upfront investments have been made. Therefore, it is unreasonable to expect the ACO to fully fund the costs of such a Beneficiary Incentive Program, and we urge CMS instead provide such funding as is the case in the Next Generation ACO Model. At a minimum, CMS should consider funding the program for the first year to support the cost of running such a program.

The BBA also requires incentive payments be made for each qualifying service. A patient could have several qualify services, and if the payments must go to all patients who receive a service, then the total cost to run a program quickly grows out of hand. We urge CMS to work with Congress to change the statute to make it more flexible so that payments could be made, for example, for just one qualifying visit, rather than all visits. Additionally, we ask ACOs be permitted to target certain high-need populations or those with a specific clinical condition to improve their care. Also, payments must be made within 30 days, increasing the administrative costs of processing claims. While CMS hasn't released data on who is operating a Beneficiary Incentive Program this year, there's reason to believe it's extremely low. The program could benefit from a few tweaks to increase its utility.

CMS should also look for ways to advance ACO access to utilization management tools allowed in Medicare Advantage. These tools encourage patients to stay within their networks to incentivize efficient and high quality care without limiting patient choice. CMS should allow the same or similar utilization management criteria present in Medicare Advantage to assure that unnecessary utilization does not occur, for example, through repeat advanced imaging, add on SNF days, and other medically unnecessary services. This is consistent with CMS-intended controls through requirements under the Protecting Access to Medicare Act of 2014, including appropriate use criteria.

Indefinite Basic Track Level E Participation and Voluntary Enhanced Track Participation

Key comment: NAACOS urges CMS to allow indefinite participation in Basic Level E and make the Enhanced Track voluntary.

Comments**:** NAACOS strongly supported the introduction of Track 1+ as a risk-based ACO model with risk levels more appropriate for providers, and we were very pleased to see it carried over as Basic Track Level E under the new Pathways to Success program structure. Level E is an important step to support the long-

term viability of the ACO model and qualifies as an Advanced APM under MACRA. However, under current program rules, ACOs may only participate in Level E for up to five or six years before having to move to the Enhanced Track, which requires a significant jump in risk. Many ACOs that participate in Level E will not be prepared to assume greater levels of risk in other ACO models in the future. Further, Level E meets the nominal risk criteria under the MACRA QPP and should be enough for indefinite participation. As such, participation in Level E should not be restricted to a specific number of years. The MSSP is a voluntary program and trying to force ACOs to assume higher levels of risk in the Enhanced Track will not work for many ACOs. They will quit the program rather than take on risk they are not prepared for. We urge CMS to modify the MSSP program rules to keep participation in the Enhanced Track voluntary.

Medium Priority Items:

Merit-Based Incentive Payment System (MIPS) Transparency

Key comment: Provide more transparency to ACOs regarding MIPS scores and provide ACOs with the opportunity to appeal scores when appropriate.

Comments: The QPP has been in existence for three performance years, and thus far the lack of transparency regarding how CMS calculated MIPS performance scores has been insufficient. In particular, ACOs are unable to see detailed performance information for ACO practices and clinicians. On many accounts, ACOs have questioned their final MIPS scores and requested to obtain the calculations for their scoring. CMS has reported they are unable to provide this level of detail.. Additionally, there is no recourse for the ACO should they feel their score is incorrect based on their own internal calculations of performance. Therefore, we demand CMS provide ACOs with calculations for all four categories of performance in MIPS and provide an appeals process for ACOs who identify errors in their published MIPS scores.

ESRD Benchmark Category

Key comment: Modify the process to classify ACO beneficiaries with end stage renal disease (ESRD) for ACO benchmarks.

Comments: 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 often 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. 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 in ACO benchmarks. 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.

Fraud and Abuse

Key comment: NAACOS requests CMS allow ACOs direct access to CMS program integrity to report suspected fraud and abuse.

Comments: 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 about 21,000 lives and includes hundreds of clinicians. Its success depends on an ACO continuously monitoring its Medicare spending. 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 provides ACOs a frontline perspective to identify and report suspicious activity. However, ACOs 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.

A July 2019 report from the OIG made a similar recommendation. It suggested that CMS give referrals of suspected fraud and abuse from ACOs a heightened level of attention. CMS stated in a July 18 congressional hearing that it would create a fast-track process for value-based model providers, such as ACOs, to report potential fraud, and we urge the agency to do so as soon as possible.

MIPS Regulatory Burdens on ACOs

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

Comments: CMS currently excludes Track 1 and Basic Track Levels A, B, C and D ACOs from the Advanced APM category of the QPP. Therefore, these ACOs are subject to both MSSP requirements as well as QPP requirements, specifically MIPS requirements. Because these 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 they participate in. Instead, CMS should provide ACOs with full credit for the quality reporting category of MIPS automatically. ACOs are already evaluated on quality in the context of the MSSP and therefore should not be subjected to an additional set of quality analysis in a separate program.

We applaud CMS for enacting NAACOS' recommendations to allow an annual attestation process for MSSP ACOs to prove they are using certified electronic health record technology (CEHRT). Making this change has the potential to save ACOs significant time and resources to devote instead to improved clinical care. However, we want to call to CMS's attention an issue that negates this improvement. Due to the timing of QP status notifications, ACOs do not know whether they meet QP thresholds in time to avoid reporting MIPS Promoting Interoperability (PI) measures. ACOs in Advanced APM models therefore must still have their practices report on all MIPS PI requirements. Advanced APM ACOs therefore must still have their clinicians submit all required PI measures, engage in ongoing education to support this reporting and submit the new annual ACO CEHRT attestation. This has had the unintended consequence of adding burden to Advanced APM ACOs instead of reducing regulatory burden. As a result, we request CMS exempt all clinicians in Advanced APM ACOs from PI reporting requirements and instead award them automatic full credit for this performance category.

Finally, CMS must make all program criteria and scoring methodologies as they pertain to ACOs specifically, accessible and transparent. Currently, QPP Help Desk staff and community supports often provide clinicians in ACOs with incorrect information about how MIPS requirements and exemptions apply to them. CMS

must make a concerted effort to educate Help Desk staff and community-based supports for the QPP familiar with how MIPS requirements apply to ACOs and clinicians in ACOs specifically.

Data Use Agreements (DUAs)

Key comment: NAACOS urges CMS to remove the approval process to add a party to a DUA.

Comments: We urge CMS to simplify the process for amending the list of parties covered under an ACO's DUA, specifically to allow ACOs to add parties without having to wait for CMS 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. The time delay and uncertainty impedes an ACO's ability to work with the new vendor or organization, inhibiting an ACO's operations and 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 ACO 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 healthcare 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. 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 Mechanisms

Key comment: NAACOS urges CMS to remove the requirement for tail period coverage and lower the repayment mechanism amounts for Basic Track Levels C, D, and E. NAACOS requests that CMS provide new repayment mechanisms, including reinstating reinsurance and introducing an option for a future withhold of Medicare payments.

Comments: Securing a repayment mechanism is a regulatory burden, which is time consuming and costly for ACOs. Many ACOs cite the burden and cost of securing a repayment mechanism as reasons not to move to a risk-based ACO model. Instead of requiring a repayment mechanism that pays banks and brokers and takes money away from the ACO's core mission of improving patient care, we urge CMS to remove the repayment mechanism requirement when an ACO can prove that it has an investor or financial backer with a demonstrated high credit rating. Financial backers could include outside investors, insurers, hospitals, or health systems that are involved with the ACO and providing financial support, which would be available should losses occur. This assurance would protect the Medicare Trust Fund in the event the ACO has losses while avoiding the financial inefficiency and regulatory burden of involving outside financial institutions as third parties that benefit from the repayment mechanism requirements. This would also eliminate the need to have a 12-month tail period required under the Pathways rules, which is an added burden.

Should CMS retain the repayment mechanism requirements, we urge the agency to provide flexibility for ACOs that may need to adjust their repayment mechanisms over time. For example, CMS should work with ACOs to provide flexibility to release funds for a limited window, such as 60 days, for ACOs changing repayment mechanisms. Updating repayment mechanisms may happen over time as a result of organizational changes, needs, and availability of specific repayment mechanisms.

We also request that CMS provide new repayment mechanisms, including introducing an option for a future withhold of Medicare payments as repayment mechanisms. Additionally, CMS should restore reinsurance as a qualifying repayment mechanism, which it was until CMS removed it in the June 2015 final MSSP rule. The agency's rationale for doing so was that few ACOs were using this option. However, we question that logic considering how few risk-bearing ACOs there were at that time. Further, despite limited initial use of reinsurance for demonstrating ability to repay losses to CMS, this continues to be an option

which some ACOs pursue separate from their CMS obligations. Therefore, we see no harm in CMS reinstating reinsurance as an option, and we urge CMS to do so for all two-sided ACO tracks/models.

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. Furthermore, 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. 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 Provider Enrollment, Chain and Ownership (PECOS) view-only access to ACOs to view information on Tax Identification Number (TIN)/National Provider Identifier (NPI) data for ACO participants.

Comments: Participation in the MSSP requires all suppliers in a TIN to participate. 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 or leave a TIN, it is essential that they, or their respective group practices, update the related Medicare enrollment records in the 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 healthcare 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 and 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 and should be automatically given view-only access to PECOS for ACO participant TINS and NPIs. Providing this information would not only help ACOs but would benefit CMS by encouraging the ACO TINs to keep their PECOS information up to date in the PECOS database.

Conclusion

In closing, we appreciate the agency's ongoing attention to reducing regulatory burdens for healthcare providers. NAACOS looks forward to working with CMS to implement the changes we have recommended to ensure ACOs can continue to focus their time and attention to serving patients by reducing regulatory burdens.

Sincerely,

Allison Brennan

Allison Brennan, Vice-President of Government Affairs