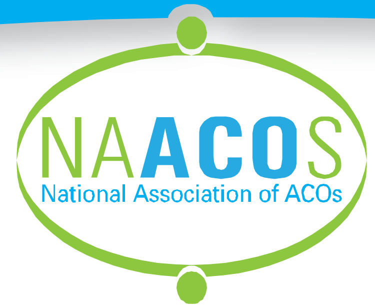

April 19, 2017

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

Re: CMS-5519-IFC; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement (CJR) Model; Delay of Effective Date

Dear Administrator Verma:

The National Association of ACOs (NAACOS) appreciates the opportunity to provide feedback on the delay of the final rule, "Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement (CJR) Model." NAACOS not only supports the delay of the implementation of these new EPMs but we also ask CMS to suspend the implementation of this rule indefinitely until further study has been done to evaluate the potential unintended consequences of these expansive new, mandatory models.

NAACOS is the largest association of ACOs, representing over 3.3 million beneficiary lives through 233 Medicare Shared Savings Program (MSSP) ACOs, Next Generation, and commercial ACOs. NAACOS is an ACO member-led and member-owned non-profit organization that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health and outcomes, and health care cost efficiency. 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.

The issue of episode and bundled payment overlap with ACOs is of critical importance to our members. The overlap of ACOs with bundled payment initiatives such as the mandatory bundles created in the EPM rule creates a clear conflict with the ACO model. While we support voluntary bundled payment models, we strongly oppose CMMI's use of mandatory bundled and episode-based payment models. The scope of these programs is vast, and the current policies related to the intersection of bundles and ACOs hampers ACOs' ability to succeed.

The policies CMS has created regarding this overlap are slowly eroding the health care industry's greatest opportunity for creating true health care delivery system redesign; population health-focused models such as ACOs. In order to protect the care redesign efforts already underway in hundreds of ACOs across the

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country, we urge CMS to make the following policy changes, which are further detailed in our comments below:

- Revise the current overlap policy to exclude all ACO beneficiaries from episodes and/or bundles unless a collaborative agreement exists between the bundler and the ACO
- Delay implementation of new episode and bundled payment models indefinitely until further study has been done to evaluate the potential unintended consequences of these models in the marketplace as well as the impacts of overlap with existing models
- Modify model requirements to make participation in these episodes voluntary, rather than mandatory
- Implement a strategy for value-based payment reform where new initiatives do not harm existing initiatives, but instead advance and leverage current efforts and resources being deployed
- Refrain from moving forward with any plans to expand or implement a new version of the Bundled Payments for Care Improvement Initiative (BPCI)

Revise the current overlap policy to exclude all ACO beneficiaries from episodes and/or bundles unless a collaborative agreement exists between the bundler and the ACO

NAACOS urges CMS to address the problematic interactions resulting from the overlap of ACOs and bundled and episode payment models that cause negative unintended consequences undermining ACOs and their ability to succeed. CMS policy should promote the growth of population-based payment models that take responsibility for the entirety of patients' care needs and invest in care coordination and prevention efforts throughout the year, thus reducing costly care such as avoidable hospitalizations or procedures.

Under current CMS policy, a bundled payment participant maintains precedence, or financial responsibility for the bundled payment episode of care. Any gains or losses during that episode are linked to the bundled payment participant and are removed from ACO results during year-end financial reconciliation. In the case of the BPCI, when CMS calculates an ACO's shared savings, the spending for ACO patients with an episode of care provided by a bundled payment participant is set to that bundler's target price, regardless of actual spending. Target prices based on higher cost baselines arbitrarily raises an ACO's performance cost and removes their saving opportunity. At the same time, certain ACOs can benefit from bundled payment program overlap if a bundle target price is lower than the ACO's actual spending. While this impact may be favorable or unfavorable for an ACO depending on its costs relative to those of the bundlers in its market, the net effect skews accountability for population-based models and in general undermines an ACOs' opportunity for savings through care redesign since any savings would automatically go to the bundler.

For CJR and EPM episodes, CMS will attribute savings achieved during an EPM episode to the EPM participant, and it will include EPM reconciliation payments for ACO-assigned beneficiaries as ACO expenditures. NAACOS continues to oppose this approach as it unfairly penalizes ACOs. Under current policy, CMS will make an adjustment to the reconciliation amount to account for any of the applicable discount for an episode resulting in Medicare savings that is paid back through shared savings under the MSSP or any other ACO model, but only when an EPM hospital also participates in the ACO and the beneficiary in the EPM episode is also assigned to that ACO. In these cases, CMS will reclaim from the EPM participant any discount percentage paid out as shared savings for ACOs when the hospital is an ACO participant and the beneficiary is aligned with that ACO. The agency explains that this adjustment is necessary to ensure that the applicable discount under the EPM is not reduced because a portion of that discount is paid out in shared savings to the ACO and thus, indirectly, back to the hospital. This overlap policy puts ACOs at a disadvantage and unfairly penalizes the ACO that is also invested in coordinating EPM patients' care.

The problem is further exacerbated by the fact that the 60 to 90-day patient episode of care is carved out of the ACO's provider network and there are no requirements for the bundler to transition the patients or their medical records back to the ACO to which they are assigned. This policy provides bundled payment participants with little or no incentive to collaborate with ACOs, a situation that threatens the continuity of care for patients. CMS argues that prioritizing bundled payment programs helps assure adequate sample size for bundlers. However, much of the variation in per-episode spending results from the utilization of post-acute care or readmissions, both of which ACOs are often instrumental in managing or preventing. ACOs focus on, and make considerable investments in care coordination and improving care transitions to manage post-acute care effectively. Many successful ACOs credit these efforts for allowing them to achieve shared savings. What's more, bundled payment models focus solely on per-unit costs rather than total cost thereby leaving the very important issue of volume unaddressed. For these reasons, we argue that instead CMS should prioritize ACOs and other value based payment models which focus on population health and total cost of care in addition to specific conditions or procedures. Should CMS not make these changes, then at a minimum, CMS should exclude EPM reconciliation payments from ACO expenditures.

While bundled payments may be able to deliver savings over the short term, placing an emphasis on programs that do not address volume or total cost of care could undermine the success of ACOs in the long term. Additionally, bundled payment models do nothing to incentivize clinicians to focus on preventing the condition or procedure. ACOs help to prevent adverse health conditions and therefore can eliminate the need for a procedure or prevent a patient from developing a condition that an episode model may address. By holding episode participants responsible only for a single episode of care, CMS leaves the Medicare Trust Fund susceptible to aggregate overspending resulting from increased volume. In contrast, ACOs are responsible for total cost of care and therefore have a large incentive to address unnecessary spending and utilization of procedures being performed.

As stated in our previous comments on this final regulation, we urge CMS to exclude all ACO beneficiaries from bundles unless a collaborative agreement exists between the bundler and the ACO. CMS cites the lack of prospective patient attribution as a potential administrative issue preventing the agency from excluding ACO assigned beneficiaries from bundles. However, we question the claim that prospective alignment would be necessary in order to exclude ACO beneficiaries from bundled payment programs when a collaborative agreement is not in place. These beneficiaries could be identified in the HIPAA Eligibility Transaction System (HETS) as being prospectively or preliminarily assigned to an ACO, which would indicate to a bundler that these beneficiaries would not be participants in the bundled payment program. This requirement would ensure an optimal outcome by bringing both parties to the table to work together to collaboratively design care coordination processes and enhance beneficiary outcomes. Further, it would incentivize hospitals to determine the best way to provide information on beneficiary admissions to primary care providers, thus involving primary care providers as early as possible to manage care and prevent adverse events and costly readmissions.

On page 50869 of the final EPM rule, CMS states, "We do not believe that testing a new approach to addressing overlap, which could potentially disrupt ACO investments, operations, and care redesign activities, would be appropriate at this time prior to a test with a smaller population. We plan to monitor and learn from the test of excluding beneficiaries prospectively assigned to an ACO from risk tracks and consider these results and comments in future rule-making." While CMS is reluctant to test a new approach across ACOs, the agency does not have any reluctance to testing mandatory bundled payments on a large scale. The new EPM rule would require mandatory participation in 98 MSAs, which is in addition to the significant participation already required for CJR in 67 Metropolitan Statistical Areas (MSAs). Additionally, no new episode or bundled payment models should be introduced until and unless CMS is able to thoroughly evaluate the impact of bundles on ACOs. Should the agency move forward with such a large scale rollout of the new EPMs and expanded CJR, we urge CMS to move just as quickly to protect ACOs

from the unintended negative consequences of this program overlap before it's too late. Not doing so would certainly disrupt ACO investments, operations and care design activities.

Finally, on page 50868 CMS states its desire to "preserve the integrity of ongoing model tests without introducing major modifications that could make evaluation of existing models more challenging." The overlap of bundled payment programs and population-based programs such as ACOs certainly compromises the integrity of ongoing programs as well as limits the ability to properly evaluate the effect of each program. The overlap of these models makes it very difficult to evaluate their separate outcomes, which will become increasingly important as CMS considers which models to expand and focus on in the future.

Delay implementation of new episode and bundled payment models indefinitely until further study has been done to evaluate the potential unintended consequences of these models in the marketplace as well as the impacts of overlap with existing models

To date, CMS in conjunction with the Centers for Medicare & Medicaid Innovation (Innovation Center) has released numerous episode and bundled payment tests in rapid succession without pause to study the results and impact of such tests. For example, CMS has yet to release a thorough analysis of the BPCI. We believe CMS should not move forward with any new bundled or episode payment models until CMS releases their comprehensive analysis of the BPCI experiment. CMS' swift expansion of bundled and episode payment models has the potential to disrupt and compromise the success of other CMS initiatives currently underway, such as the MSSP and other ACO models.

NAACOS calls on CMS to conduct a rigorous analysis to determine the effect of overlapping value-based programs, including the interplay between bundled payment programs and ACOs before moving forward with additional programs. When evaluating bundled payments, it is critical that CMS not only focus on spending changes for the bundled payment episode but also examine any potential changes in overall volume of these episodes. Further analysis must be done to take total cost and volume of services into account.

A recent study, "*Association Between Hospital Participation in a Medicare Bundled Payment Initiative and Payments and Quality Outcomes for Lower Extremity Joint Replacement Episodes,"* published in the Journal of the American Medical Association (JAMA) on September 19, 2016 examines hospitals in BPCI and their quality results and expenditures. The study compared changes in spending, utilization, and quality for Medicare beneficiaries who underwent lower extremity joint replacement during a baseline period before the BPCI initiative was launched (October 2011 through September 2012) and the early intervention period (October 2013 through June 2015). While there was no meaningful difference with quality results (claims-based quality measures were nearly identical at baseline in BPCI and control hospitals and changed in similar ways during the intervention period), the study did find statistically significant results for spending and utilization.

A major finding of the study was that while spending decreased in both the intervention and control populations, the spending decrease for lower extremity joint replacements was significantly greater for health care organizations in BPCI. However, further analysis that takes into account the total volume of bundles showed that total spending actually declined less in the BPCI hospitals than in the comparison hospitals. We urge CMS to further explore this in future analysis. In addition, CMS must publish the data necessary for outside researchers to evaluate the effects of bundles on total overall costs and total volume.

Modify model requirements to make participation in episodes voluntary, rather than mandatory

At a minimum, CMS must make modifications to the current EPM rule policy to make these models voluntary rather than mandatory. Making these programs mandatory not only unfairly forces providers to take on financial risk for these episodes, but also broadens the reach of these models exponentially. Until CMS and the health care industry at large are able to study the impacts of the interactions among the plethora of bundles and episodes entering the marketplace, it is unwise to continue introducing additional episode models on such a large scale. The broad reach of these programs creates the potential to also have a large impact on the marketplace in general as well as other health care delivery redesign efforts currently underway, like the efforts of ACOs.

Further, we question if CMS has the authority under Section 3021 of the Affordable Care Act to mandate EPM bundles as proposed. CMS does not have the authority to implement a demonstration that harms a permanent Medicare program such as the MSSP. We are very concerned about the negative impact of this policy on ACOs and recommend CMS reconsider the use of mandatory demonstrations in general.

Implement a strategy for value-based payment reform where new initiatives do not harm existing initiatives, but instead advance and leverage current efforts and resources being deployed

CMS will discourage provider participation in Alternative Payment Models (APMs) by rapidly introducing new models that undermine the efforts of those currently in existence. It is no small effort to participate in care redesign efforts. ACOs require significant investments including start-up and operating costs to help fund critical ACO activities designed to improve beneficiary care, enhance care coordination, and reduce unnecessary spending and hospitalizations. A survey of our members find these costs to be significant, with an average estimate of $1.6 million in annual operating costs attributable to participation in the MSSP. Implementing competing programs without policies to protect those already in existence will create confusion, add administrative complexities and dilute the savings opportunities for those already on the forefront of care redesign. Therefore, we urge the new administration and CMS to implement a strategy for value-based payment reform where new initiatives do not harm existing initiatives but instead advance and leverage existing initiatives and resources.

Refrain from moving forward with any plans to expand or implement a new version of BPCI

While not formally proposed in this rule, CMS discusses building on BPCI, stating that CMMI intends to implement a new voluntary bundled payment model for 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM. The same concerns about bundled payment overlap with CJR and EPMs also apply to BPCI, and we recommend CMS exclude ACO assigned beneficiaries from new voluntary bundles unless a collaborative agreement is in place between an ACO and hospital that is not a participant in that ACO. What's more, CMMI is charged with implementing demonstrations of adequate sample size to implement the particular demonstration. The scale of BPCI certainly reaches this threshold, therefore it is unnecessary for CMS and CMMI to add additional bundled payment tests to the marketplace, especially those with national scope such as the mandatory EPMs created by this regulation. Doing so only makes evaluation of these competing models more difficult and creates problems of overlap as highlighted in our comments.

Should CMS move forward with another iteration of BPCI or similar voluntary bundled payment model, we urge CMS to allow ACOs to be applicants for any new voluntary bundled payment programs. Doing so would allow ACOs to effectively manage the bundled payment episode as well as the patient's care throughout the year. It makes little sense to arbitrarily divide bundlers and population-based healthcare providers when in reality ACO providers should be able to be responsible for a bundle within a population-based model. Effectively managing a bundle within a performance year would reinforce the objectives of

the ACO and would likely generate more savings for Medicare. We also urge CMS to re-evaluate the role of conveners with respect to bundled payment programs such as BPCI. Specifically, we have concerns that allowing private for-profit awardee conveners to absorb the risk for providers adds an unnecessary layer to our healthcare system without benefiting patients or Medicare. CMS should exclude for-profit risk-taking conveners who do not provide patient care. We do not share the same concerns about facilitator conveners who do not take risk for the bundlers and instead serve as an aggregator to bring a group of participants under one application and help to implement consistent delivery reform efforts across the group of participants.

Conclusion

In conclusion, it is critical that CMS protect the investments and efforts of ACOs by creating program overlap policies that do not undermine ACO efforts. Additionally, no new episode or bundled payment models should be introduced until and unless CMS is able to thoroughly evaluate the impact of bundles on ACOs. With the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) accelerating the proliferation of new and innovative payment models, CMS must create a strategy for value-based payment reform where new initiatives do not harm existing initiatives, but instead advance and leverage current efforts and resources being deployed. We urge CMS to prioritize population-based payment models like the MSSP and Next Generation ACO Models, as this is the greatest opportunity to focus on total cost of care and truly transform how health care is delivered. We appreciate the opportunity to comment on this important issue.

Sincerely,

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