May 20, 2020

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-1744-IFC, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and CMS-5531-IFC, Additional Policy and Regulatory Revisions in Response to the COVD-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

Dear Administrator Verma:

The National Association of Accountable Care Organizations (NAACOS) is pleased to provide our comments in response to the Interim Final Rules with comment period (IFC) making policy and regulatory revisions related to the COVID-19 Public Health Emergency (PHE). We appreciate the significant efforts underway by the Centers for Medicare & Medicaid Services (CMS) to address the COVID-19 pandemic, including expanded telehealth services to help ensure the safety of patients and enacting the extreme and uncontrollable circumstances policy for the Medicare Shared Savings Program (MSSP).

As the largest association of ACOs, NAACOS and its ACO members serve more than 12 million beneficiary lives through hundreds of organizations participating in population health-focused payment and delivery models in Medicare, Medicaid, and commercial insurance. NAACOS and its members are deeply committed to the transition to value-based care. NAACOS is an ACO member-led and member-owned non-profit organization that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health and outcomes, and healthcare efficiency.

As clinicians, hospitals, Alternative Payment Model (APM) participants and the health care industry as a whole focus on responding to the COVID-19 PHE, it is critical that CMS takes the appropriate steps to ensure this pandemic does not derail the APM and value movement. We support CMS's decision to make additional adjustments to the extreme and uncontrollable circumstances policy for MSSP to protect ACOs during this challenging time. Doing so will enable ACOs to be part of the solution when recovering from this pandemic. While there are many helpful policies in the IFCs, we

urge additional action from CMS to fully protect ACOs and ensure continued program success. Specifically, we request the following actions be swiftly taken by the agency, as detailed further in our letter below:

- Adopt a policy to give ACOs an option to be protected from losses in exchange for a reduced shared savings rate, no less than 40 percent;
- Extend the current June 30 deadline to exit the program to avoid financial losses to no earlier than October 31;
- Make all ACO quality measures pay-for-reporting in 2020;
- Provide an option for new ACOs to join the MSSP in 2021 by introducing an April 1 or July 1, 2021 start date;
- Extend the Next Generation ACO Model for at least one additional year;
- Pay ACO shared savings payments and Advanced APM bonuses as soon as possible;
- Clarify that all codes used for ACO assignment listed in §425.400(c)(1)(iv) will be counted in beneficiary alignment even when delivered via telehealth;
- Revise the benchmarking methodology to remove ACO beneficiaries from the regional population used for regional benchmarking;
- Update risk adjustment so that positive risk score increases would be subject to a cap of no less than 5 percent and negative risk score adjustments would be between 0 and negative 5 percent; and
- Remove the ACO beneficiary notification requirement for 2020.

Additional Flexibility in Participation Options

We thank CMS for taking action to provide more flexibility to ACOs during the COVID-19 pandemic. We strongly support the option provided to ACOs with agreements ending December 31, 2020, to extend their agreements for an additional performance year (PY). We also greatly appreciate CMS enacting a policy to allow ACOs to remain in their current risk level for an additional year, a policy NAACOS supports. For the latter, in PY 2022, we request that ACOs only move up to the next level in the glide path and not jump to the level they are currently on track for in performance year 2022. These actions will provide much needed flexibility to ACOs in an uncertain time.

Given the unprecedented variability in spending presented by the COVID-19 PHE and the lack of clarity regarding when the PHE may end, we urge CMS to give ACOs additional participation options. Specifically, CMS should adopt a policy to provide ACOs an option to be protected from losses in exchange for a reduced shared savings rate, no less than 40 percent. Despite the protections provided in the IFCs, many ACOs remain concerned about the unpredictability and potential for catastrophic losses for PY 2020. Providing the flexibility of this option would prevent ACOs from quitting and maintain the savings ACOs generate for Medicare.

Additionally, we urge CMS to extend the current June 30 deadline to exit the program to avoid financial losses to no earlier than October 31, 2020 (with no more than a 30-day notice, as is currently required). This will allow ACOs to have more time, and therefore more data, to make an informed decision on whether they must leave the program. Given the current PHE is set to expire in July and it is anticipated a resurgence of the virus is possible in the fall, it will be critical for CMS to provide ACOs with this additional time to be able to make an informed decision about their continued participation in ACO models. This will also provide ACOs with more time to focus on the

pandemic and remain in the program. At a minimum, CMS should provide 90 days from the date of the second IFC to allow ACOs time to consider the program adjustments recently released by the agency. We must preserve the move to value by giving ACOs the flexibility and time they need to navigate this challenging and unpredictable time.

Evaluating Costs

We are pleased CMS has adjusted the MSSP extreme and uncontrollable circumstances policy for the COVID-19 pandemic by also removing payment amounts for months affected by COVID-19 episodes of care, as identified by inpatient care for treatment of COVID-19, from MSSP performance year expenditures, while making updates to the historical benchmarks and revenue calculations for determining loss sharing limits for certain ACOs. These changes will create more equitable cost comparisons and more accurately reflect the care ACOs are providing during this unprecedented pandemic. However, NAACOS remains concerned that these adjustments will only be made for the duration of the PHE. This creates uncertainty because the PHE's duration is only extended through July at this time. NAACOS believes it would be more accurate to extend this policy through the remainder of 2020 and reevaluate whether additional adjustments may be necessary extending into 2021. This would provide certainty to ACOs who are facing a June 30 deadline to leave the program and avoid financial reconciliation.

CMS must provide as much certainty as possible during this unpredictable time to ensure ACOs are not held accountable for costs related to this global pandemic. Additionally, we urge CMS to clarify that an episode can be triggered when a COVID-19 diagnosis code is present and does not need to be the primary diagnosis code to trigger the episode. This will be critical as there has been a large amount of variability in the manner in which COVID-19 diagnoses are listed on claims, due to the often multi-system nature of COVID related illnesses. We also urge CMS to clarify that an episode will be triggered by acute care inpatient services for treatment of COVID-19 from facilities not paid under the Inpatient Prospective Payment System (IPPS), including Skilled Nursing Facilities, when the date of admission occurs within the COVID-19 PHE.

There will be long lasting effects of the COVID-19 pandemic on ACO costs, unmanaged chronic conditions as non-COVID patients avoid seeking care and the resulting issues with patient attribution, and risk adjustment that result from this avoidance of care. Additionally, as many elective procedures are being postponed to reserve Personal Protective Equipment (PPE) and to prevent exposure, many of these elective procedures will be moved to the period following the PHE, adding to the increased costs ACOs may be held accountable for in the future. Finally, the COVID-19 pandemic is disproportionally affecting the Medicare population, putting ACOs at even more financial risk for these additional costs. CMS will need to address these program areas in the months and years ahead, after careful study of the impact on ACOs across the nation. NAACOS urges CMS to work closely with the ACO stakeholder community to evaluate and modify key program aspects to adequately adjust them for these long-term COVID-19 implications. We also urge CMS to evaluate the need for additional support measures for patients with COVID-19, such as additional upfront funding to manage patients in recovery.

Quality Assessments

The extreme and uncontrollable circumstances policy will make minimal changes to an ACO's quality assessments in 2020. Specifically, if an ACO is unable to report quality due to the extreme and uncontrollable circumstance, the ACO's quality score will be set to the mean quality performance score for all MSSP ACOs for the applicable performance year. However, if the ACO is able to completely and accurately report all quality measures, CMS will use the higher of the ACO's quality performance score or the mean quality performance score for all MSSP ACOs. While this approach may have been suitable for a natural disaster, such as hurricanes that are more regionally focused, this is not an appropriate policy solution for the COVID-19 pandemic we are currently facing.

The avoidance of care by patients and postponement of certain critical services to preserve PPE will have lasting effects on quality. In addition, well visits are also being postponed. As a result, ACOs will struggle to manage patients with chronic conditions and provide proper preventive care during this time. For these reasons, it would not be appropriate to compare performance to quality benchmarks, which were established in previous years. Finally, many ACOs are deploying their quality improvement staff to provide clinical care and assist in triaging patients, detracting them from their more typical quality improvement and care coordination work. As a result, NAACOS does not feel the extreme and uncontrollable circumstances policy goes far enough to mitigate the vast impact of the COVID-19 PHE on ACO quality measures, and we instead urge the agency to make all measures pay-for-reporting in 2020. There is value in reporting what data ACOs can during this challenging time. However, ACOs should not be held accountable to typical quality standards during this highly irregular pandemic. We also urge CMS to continue to study the impact of the pandemic on ACO quality in the months and years to come, as it is likely additional policy changes will be necessary in the future.

Application and Program Deadlines

We thank CMS for providing ACOs with additional program participation flexibilities due to the COVID-19 pandemic. In particular, we applaud the decision to allow ACOs to remain in their current risk level for one additional year given the highly irregular and unpredictable nature of spending as a result of the COVID-19 PHE. We are, however, very disappointed with the decision to forgo a 2021 application cycle. Given all ACOs are facing with the COVID-19 pandemic, applying for participation in APMs for 2021 would be challenging with the typical deadlines, but the more appropriate solution would have been to extend those deadlines rather than cancel the application cycle altogether. We urge CMS to implement a PY 2021 application cycle with an April 1, 2021, or July 1, 2021 start date for those ACOs who are able to submit application materials in the summer and fall of 2020. As detailed in this letter, we also strongly request that the Centers for Medicare and Medicaid Innovation (Innovation Center) extend the Next Generation ACO Model for at least one additional year.

Moving these deadlines will ensure ACOs are able to continue to participate in these premier APMs. Losing momentum in the value-based movement would be a very harmful consequence of this pandemic that can be remedied with quick action by CMS and the Innovation Center. We also urge CMS to expedite 2019 ACO evaluations and ensure shared savings payments are also expedited to provide additional relief to ACOs. We also urge CMS to expedite payment of Advanced APM bonuses, which could be used as a lifeline to ACOs struggling during this challenging time.

Beneficiary Notification

We urge CMS to remove the beneficiary notification requirement for 2020. While we are pleased CMS is using its enforcement discretion to give ACOs until the end of the performance year to provide the notifications, we feel this does not go far enough in relieving this very burdensome requirement at this difficult time. As NAACOS has noted, this requirement is burdensome and costly in even the best of circumstances. Given the resources needed to combat COVID-19, we ask that CMS remove this requirement.

Benchmarks

COVID-19 has a varying impact across different parts of the country and on certain localities within the same area. This regional variation highlights existing problems with ACO benchmarks, which should be based on reliable regional data. NAACOS urges CMS to utilize upcoming rulemaking, such as the 2021 Medicare Physician Fee Schedule, to finally address ongoing benchmarking flaws that are illustrated by the current pandemic.

NAACOS supports many aspects of the MSSP benchmarking methodology, such as using historical and regional expenditure data. If executed correctly, benchmarks with a blend of historical and regional expenditure data will attract new ACOs while retaining existing participants and ultimately improve the long-term viability of the program. However, there have been ongoing concerns with CMS's approach to calculating regional costs, which is a critical component of benchmarks. Under current policy, CMS includes ACO beneficiaries in the regional component of the benchmark, which means the ACO is compared to itself twice: once using historical ACO spending and another time by including ACO spending in the regional spending. This is contrary to the goal of a regional benchmark, which is to compare the ACO to other providers in its region.

In an attempt to address this concern in the 2018 *Pathways to Success* regulation, CMS moved to a blended national and regional trend rate, with the blend determined by averaging the market penetration across all counties where the ACO has assigned beneficiaries. The result is a methodology that often over-emphasizes the national trend component for ACOs that comprise a large market share, which is frequently the case in rural areas. Relying too heavily on a national trend is especially problematic during a pandemic with regional variation as it ignores important local market dynamics that differ across the country. ACOs in COVID hot spots will likely have higher costs than the overall nation. Therefore, using the national trend as part of the benchmarking methodology will be detrimental and unfair to these ACOs as it is not reflective of the pandemic's effect on costs in their region.

This current policy does not address the underlying problem caused by including ACO beneficiaries in the population from which the regional expenditure data is drawn, and as noted above is exacerbated by COVID-19. In fact, a simpler solution to the complicated and confusing national-regional trend rate would be to remove ACO beneficiaries from the regional reference population, as NAACOS and many others have previously recommended. By excluding ACO beneficiaries from the regional reference population, the situation where an ACO is being directly evaluated against itself within the same performance year is eliminated. This creates a cleaner comparison for benchmarks by comparing ACO spending to spending in the ACO's region, based on the remaining fee-for-service beneficiaries. This is the general approach CMS takes with Medicare Advantage.

This benchmarking flaw is often referred to as the "rural glitch" because rural ACOs are frequently harmed by the policy, although it disadvantages efficient ACOs with high market penetrations that are not in rural settings. There are currently two bills in Congress that would fix this benchmarking flaw, the *Accountable Care in Rural America Act* (H.R. 5212) and the *Rural ACO Improvement Act* (S.2648). In sum, we urge CMS to modify the MSSP benchmarking methodology by comparing ACO performance relative to fee-for-service Medicare by defining the regional population as assignable beneficiaries without ACO-assigned beneficiaries for all ACOs in the region.

We also request that CMS work closely with ACO stakeholders to evaluate methodological adjustments to future benchmarks to properly account for the effects of COVID-19. It is unclear at this point what the long-term implications will be for beneficiaries and our healthcare system, and further benchmarking adjustments may be necessary to account for the pandemic for ACO evaluations. NAACOS is pleased to work with CMS to evaluate these long-term ramifications and help identify potential solutions.

Risk Adjustment

Accurate risk adjustment should remove or minimize differences in health and other risk factors that impact performance but are outside the ACO's control. The current pandemic highlights the need for an accurate and fair risk adjustment methodology. Many patients with COVID-19 will have serious health complications this year, which will not be reflected in overall ACO risk scores which are based on data from previous years. This highlights the need to address shortcomings in the current MSSP risk adjustment methodology, as those flaws are exacerbated based on the COVID pandemic. We urge CMS to use upcoming rulemaking, such as for the 2021 Medicare Physician Fee Schedule, to improve MSSP risk adjustment. Specifically, the agency should implement policies to update MSSP risk adjustment so that positive risk score increases would be subject to a cap of no less than 5 percent and negative risk score adjustments would be between 0 and negative 5 percent.

CMS's current policy allows risk scores to increase up to 3 percent across the five-year agreement period. This minor increase when applied across the agreement period is unreasonably low, and many ACOs will see risk scores increase much more than 3 percent. With the current pandemic, some ACOs will see an increase greater than 3 percent in the one year, thus demonstrating how insufficient the current cap is. It is essential that benchmarks reflect risk changes so that ACOs are fairly judged on their performance without being unfairly expected to manage an overall population's disease burden with virtually no changes during an agreement period. It is unreasonable to assume a provider organization, however effective, can manage a population such that patient conditions never worsen over time and it never carries a higher disease burden as will be the case for many ACOs treating a large number of COVID patients. While some beneficiaries will have higher risk scores from COVID, other beneficiaries are avoiding preventive services and screenings as well as routine primary care. This will likely result in some ACOs populations, on average, appearing sicker as healthy patients' risk data will not be captured due to this avoidance of care. Therefore, we request CMS modify the current risk adjustment policy so that the cap is no less than 5 percent for the agreement period.

The goal of the risk score cap is to minimize potential outliers and controlling for outliers is important on both the upside and the downside. This is especially necessary in the context of the COVID pandemic because of the utilization disruptions and health implications that will affect risk

scores. Additionally, the two new ICD-10 diagnosis codes, "U07.1 COVID-19, virus identified" and "U07.2, COVID-19, virus not identified," are not mapped to a Hierarchical Condition Code (HCC), which is necessary for accurate risk scores. Without that mapping, these diagnosis codes will not be reflected in risk scores, causing them to look artificially low. Therefore, CMS should also implement a floor for risk adjustment decreases, so that negative risk score adjustments would be between 0 and negative 5 percent.

Telehealth

Expansion of Codes used in Beneficiary Assignment
CMS uses more than 60 Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes for MSSP assignment and lists them in §425.400(c)(1)(iv). Of these, 51 appear on CMS's list of services eligible to be delivered through telehealth. NAACOS is appreciative of CMS's move to count certain services delivered virtually, through telehealth, virtual check-ins, e-visits, or telephone, toward MSSP assignment effective for PY 2020 and any other performance year that starts during the COVID-19 PHE. Some ACOs contain physician practices that are now conducting as many as 90 percent of their visits through telehealth. Unless CMS recognizes these telehealth visits for the purposes of patient assignment, ACOs run the risk of either losing their assigned patient populations and/or not meeting the minimum 5,000 beneficiary threshold for MSSP.

While the overlap between codes used for MSSP assignment and codes eligible for telehealth is extensive, CMS did not mention in the May 8 rule CPT and HCPCS codes previously eligible for telehealth before the PHE began. NAACOS urges CMS to clarify that the agency's existing policy has been to count all codes used for ACO assignment listed in §425.400(c)(1)(iv) even when those services that are eligible for telehealth are delivered via telehealth. These include codes for health risk assessments (96160-96161), outpatient visit for the evaluation and management for new (99201-99205) and established patients (99211-99215), transitional care management (99495-99496), and advanced care planning (99497-99498). Clarifying that these codes count toward ACO attribution will mitigate any confusion and emphasize the importance of these services in assignment.

Clarification on how to deliver annual wellness visits via telehealth
Annual Wellness Visits (AWVs, G0438 and G0439) were added as a Medicare benefit in 2011 and provide a great way to connect with patients to conduct a general health assessment, identify gaps in care, and address needs. CMS added AWVs to the list of telehealth-eligible services in the 2015 Medicare Physician Fee Schedule. However, this was done at a time when telehealth was conducted in originating sites, such as hospitals, doctor's offices, and clinics. CMS has yet to clarify how Medicare AWVs can be delivered in patients' homes when some elements of visits require a clinician's touch. This includes measuring of height, weight, and blood pressure.

Due to the importance AWVs have in maintaining satisfactory patient health, NAACOS urges CMS to provide guidance on how to conduct AWVs via telehealth while offering flexibility in documenting such telehealth visits, including allowing patient-reported vital signs like height, weight, and blood pressure. For patients who have the ability, there are apps available that very accurately capture patients' temperature and blood pressure. Absent clear guidance from CMS, our members have received inconsistent feedback from their Medicare Administrative Contractors. Given the uncertain

nature of the COVID-19 pandemic and when it might resolve, it is important for CMS to support ways to deliver fundamental services like AWVs.

Payment for audio-only telephone evaluation and management services
In the IFC, CMS explains it would waive its video requirement for certain telehealth services, allowing them to be delivered through audio-only telephone calls. NAACOS heard from members that many Medicare beneficiaries do not have access to the interactive, audio-video technology Medicare typically requires for telehealth. In order to increase access to care for these beneficiaries, CMS granted a blanket waiver pursuant to authority granted to it under the Coronavirus Aid, Relief, and Economic Security Act. Eighty-nine of the 238 services listed are eligible for audio-only.

NAACOS very much appreciates CMS listening to the concerns of stakeholders, including NAACOS, in allowing wider use of audio-only telehealth services. We hope CMS will continue to add codes to this audio-only list as it is made aware of additional services that can be safely delivered through the telephone and requests that CMS start with two transitional care management codes (99495-99496). These services are important to ensuring patients safely transition from one setting of care to another, which is especially critical during the COVID-19 pandemic.

Risk adjusting for audio-only telehealth
On April 10, CMS announced it would count diagnoses from telehealth services for risk adjustment purposes. This applies both to submissions to the Risk Adjustment Processing System and the Encounter Data System. NAACOS appreciates this policy. However, CMS made clear that services counted must be from interactive audio and video telecommunications. As more telehealth is delivered through audio-only technology and as the pandemic stretches on, it will be important for CMS to count diagnoses obtained from audio-only telehealth services for risk adjustment purposes.

For many patients, video-based visits are out of reach. Patients may not have access to the technology or broadband to conduct video-based visits. For these patients, the choice is not between a video visit and a phone visit — it is the choice between an audio visit and no visit. We urge CMS to count diagnoses obtained from audio-only telehealth services for risk adjustment purposes.

Comments on unexpected cost sharing for beneficiaries
In response to the unique circumstances resulting from the COVID-19 PHE, the HHS Office of Inspector General is allowing healthcare providers to reduce or waive beneficiary cost-sharing for telehealth visits, remote patient monitoring, and broader categories of non-face-to-face services paid for by federal healthcare programs. Given patients' cost-sharing for these services can sometimes be extremely low, it can often be more of a burden to collect these payments than it is worth to practices.

In the IFC, CMS seeks comment on how best to minimize unexpected cost sharing for beneficiaries. As CMS monitors utilization of these services and how best to refine billing rules, documentation requirements, and claims edits through future rulemaking, NAACOS urges CMS to rely on existing notification requirements and beneficiary protections such as consent. When working, these existing policies should protect patients from unexpected cost sharing.

Conclusion

We applaud CMS for its swift action to make critical adjustments to the extreme and uncontrollable circumstances policy for MSSP due to the COVID-19 pandemic. We believe more can be done to ensure the movement to value is not hampered by this PHE. NAACOS appreciates all CMS is doing to assist providers at this time, and we stand ready to assist in any way. If you have any questions, please contact Allison Brennan, Senior Vice President of Government Affairs, NAACOS at abrennen@naacos.com.

Sincerely,

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