May 4, 2021

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Ave, S.W. Washington, DC 20201

## Re: Request to Delay Mandatory Reporting of eCQMs and MIPS CQMs and Implement Changes to the Medicare Shared Savings Program Quality Overhaul

Dear Secretary Becerra:

The undersigned organizations write to express our increasing concerns with the recent changes to quality reporting for the Medicare Shared Savings Program (MSSP), which were finalized in the Final 2021 Medicare Physician Fee Schedule <u>Rule</u> (CMS-1734-P), as published in the Federal Register on December 28, 2020. Quality improvement is a cornerstone of the ACO model. In addition to reducing spending, ACOs must meet quality performance standards to be eligible to receive shared savings payments. ACOs continue to improve quality year over year, which improves patient care and helps to control costs. It is critical that policies to evaluate ACO quality are fair, appropriate and accurately reflect the work ACOs undertake to improve patient care.

While reducing the number of measures and leveraging electronic data sources for quality reporting are important goals, we have significant concerns about the MSSP quality policies finalized at the very end of 2020. The policy changes lacked adequate input from the patient, ACO, physician and hospital communities, and it is unclear how the Center for Medicare & Medicaid Services (CMS) determined that the Alternative Payment Model Performance Pathways (APP) measures are more appropriate than the current measures on which ACOs are evaluated. Quality measurement within the MSSP must focus on measures most appropriate to the program. Evaluating quality of care protects against the possibility of stinting on care which can be a concern when determining accountability for costs. We believe there is an important opportunity for CMS to revise aspects of the recently finalized MSSP policies to better support ACOs and promote high quality patient care.

The new MSSP measures may be especially sensitive to differences in clinical complexity and social risk factors across patient populations. Yet, CMS has not articulated how the agency will account for these differences, which is especially problematic since the data will be collected on an all-payer basis. This policy gap means that ACOs serving sicker and more vulnerable patients may score more poorly. Therefore, ACOs' quality performance could be misrepresented as differences in quality when variation is likely due to patient access to care or complexity. ACOs treating vulnerable populations have a different mix of payers and patients, which could cause them to appear to have lower quality. This will reduce their shared savings at a time they should be receiving more resources to combat health equity issues and more support to remain on the path to value.

As noted by CMS, the goal of evaluating ACOs though the APP is alignment. However, it makes little sense to align MSSP quality with the Merit-based Incentive Payment System (MIPS) when the goal of the Medicare Access and CHIP Reauthorization Act (MACRA) is to advance clinicians from MIPS to Advanced APMs. For performance year 2021, 40 percent of Medicare ACOs are in Advanced APMs, meaning they are exempt from MIPS. Many of these ACOs have not been evaluated under MIPS for years but will now be tied to MIPS through the APP.

The quality changes also ignore the time it takes to adopt and implement electronic measures. Therefore, key policy changes and additional time are needed to ensure that ACOs can participate successfully and that patient care is not negatively impacted. In a recent survey fielded by the National Associations of ACOs (NAACOS), where a quarter of all MSSP ACOs responded, 99 percent of ACO respondents report their ACO is concerned with the requirement to implement eCQMs or MIPS CQMs in 2022. Nearly 75 percent specifically noted they are "extremely concerned" or "very concerned".

Furthermore, while much progress has been made in the past decade, these changes come at a time when the number of MSSP ACOs is declining. For example, according to <u>data</u> released by CMS in January, the number of MSSP ACOs reached its lowest level since the Trump administration took office four years ago. To start 2021, 477 ACOs are participating in the MSSP, down from a high of 561 in 2018 and the lowest since 480 participated in 2017. The program is further threatened by these quality changes. We request CMS correct the flawed MSSP quality overhaul as an early step towards strengthening the MSSP and the overall shift to value in Medicare. We offer the following feedback and recommendations to improve the quality portion of the MSSP. These recommendations are based on input from ACOs, and specifically we urge CMS to take swift action to:

- 1. Delay the mandatory reporting of electronic Clinical Quality Measures (eCQMs) and Merit-based Incentive Payment System Clinical Quality Measures (MIPS CQMs) for at least three years.
- 2. Limit ACO reporting to ACO assigned beneficiaries only, rather than all patients across payers.
- Lower the data completeness requirements beginning at 40 percent with a gradual increase to a maximum of 50 percent for those reporting eCQMs or MIPS CQMs or explore alternative approaches.
- 4. Reassess the appropriateness of the measures included in the APM Performance Pathway (APP) measure set and solicit additional input through the Measures Application Partnership (MAP) prior to finalizing a complete set of patient-centered measures for MSSP reporting.
- 5. Clarify and establish quality performance benchmarks in advance for all ACO reporting options.
- 6. Retain pay-for-reporting when measures are newly introduced or modified.

The rushed implementation of the MSSP quality overhaul has resulted in many unanswered questions about how to satisfy the new requirements for reporting all-payer data and reporting eCQMs and MIPS CQMs. These questions remain unanswered by CMS, despite the fact that we are well into the performance year and ACOs have an option to report via eCQMs and MIPS CQMs for 2021. We are very concerned that if changes are not made as soon, multiple negative unintended consequences may come to fruition, including the following.

- 1. ACOs and their participating TINs will bear significant costs for electronic health record (EHR) and/or system upgrades and shoulder data collection burdens during the ongoing global pandemic.
- 2. ACOs could be deterred from entering the MSSP or leave the MSSP entirely.

3. ACOs may drop clinicians, particularly specialists, small practices or those treating vulnerable populations, thus excluding them from the value transition. 2022 participation decisions must be made and submitted to CMS this summer.

### Recommendation 1: Delay the mandatory reporting of eCQMs and MIPS CQMs for at least three years.

ACOs support the move to electronic reporting given benefits of reduced manual chart abstractions and reporting, but they anticipate notable barriers which outweigh those benefits, including: 1) the lack of standardization across EHRs and 2) the administrative burdens and costs associated with the new reporting requirements.

ACOs have a significant number of vendor systems from which the data would be collected. Almost 40 percent of ACOs reported that they have more than 15 EHRs across their practices/participant TINs, which exponentially complicates things. While one might assume that EHR vendor systems with 2015 Certified Electronic Health Record Technology (CEHRT) would be able to easily report the most recent version of an eCQM for MIPS with minimal manual effort, that is not the case. In addition, the CEHRT requirements do not standardize the capture and reporting of individual eCQM data elements across vendor systems, and ACOs will still need to tailor data extracts and uploads across systems and participating TINs. Nearly 70 percent of survey respondents reported that their ACO does not have software in place to assist with integrating and extracting quality data from their participating TINs' EHRs.

There is a significant amount of work that must be completed by each ACO to ensure that reliable and valid data are extracted from the various systems. In addition, it is not clear what type of data auditing will be required, what criteria should be used to report across all the TINs, or even if ACOs are required to report data for participant TINs only. Many questions also remain on the extent to which the reporting and validation can be assumed by the ACO and not the participant TINs. It is possible that ACO contracts with participating practices may require those practices to bear the burden of the data mapping, extracting, and reporting to the ACO due to contractual and legal issues of an ACO accessing data for individuals who are not within the ACO. These issues are a result of the all-payer reporting requirement; therefore we do not support this requirement, as further illustrated below.

The administrative burdens are also tied to significant costs, which will strain ACOs during a very challenging time as they continue to combat COVID-19. The resources, staff time and funding used to meet the new requirements would be much better served in other areas, such as improving patient care, responding to the COVID-19 pandemic and implementing new clinical transformations to enhance patient outcomes. Many ACOs reported that they do not know exactly how much it will cost their ACO to comply with the new requirements. However, of those who were able to provide an estimate in the survey, many identified the cost would be in the hundreds of thousands of dollars or over a million dollars.

It is important to recognize the timing of these investments. ACOs will need to fund this work upfront, which is a considerable deterrent for ACOs considering joining the MSSP or those weighing remaining in the program. Over the course of the program, an average of 35 percent of ACOs have earned shared savings, illustrating the challenging nature of the program. The uncertainty of earning shared savings means ACOs will have a difficult time funding these quality changes up front, not knowing if they will earn shared savings which are paid roughly nine months after the close of the performance year.

Given the potential impact on operating budgets, ACOs will need additional lead times to price out and build in this work, making it difficult or next to impossible for many ACOs to make this shift in 2021 for 2022. Further, given the high cost of this regulatory burden, at a minimum CMS should provide funding to ACOs to meet the requirements, or as recommended delay the shift to eCQMs or MIPS CQMs. Due to these concerns, we urge CMS to allow a gradual transition from Web Interface reporting to eCQM or MIPS CQM reporting and to delay mandatory eCQM and MIPS CQM reporting by at least three years. This transition would provide time to ensure that ACOs have the infrastructure in place and costs budgeted and for CMS to provide additional guidance and clarification on the many implementation questions.

### Recommendation 2: Limit ACO reporting to ACO assigned beneficiaries only.

Should or when the agency moves forward with eCQMs/MIPS CQMs, CMS should limit reporting to Medicare assigned beneficiaries. Data access concerns were one of the top three barriers identified by survey respondents, which is directly relevant to the expansion to all-payer data. While expansion to the broader population could provide a snapshot of care within a community, it is likely not representative of the care provided by the ACO. It's important to note that the MSSP is a Medicare program so those ACOs naturally focus their efforts on Medicare patients, causing them to target services and interventions for their assigned Medicare patient population. It is unreasonable to expect that an ACO can meaningfully influence the care provided to all individuals, regardless of payer, who are seen within a participating TIN but who are outside of ACO's purview.

ACOs are currently reviewing participant TINs and associated EHRs vendor systems; determining the extent to which their current contracts with the clinicians and groups allow them to have access and permission to report on all-payer data. They are also working to develop internal infrastructure or contracting with a company to pull the data from each TIN, complete patient matching, and clean and validate the data for aggregation for the ACO. During these analyses, ACOs are encountering numerous questions and challenges on whether they have the necessary permissions to report on all-payer data and data integrity could be impacted. Concerns include:

- How should an ACO handle instances where they have a contract with the TIN providing care to the ACO's attributed patients, but where the ACO does not have contracts with all of the payers in the TIN's full patient panel?
- To what extent will data validity and resulting performance scores be impacted in instances where the ACO may not have permission to receive protected health information, and therefore the aggregated data may include duplicates due to their inability to complete patient matching?
- How should an ACO handle patients who opt out of data sharing?
- Can an ACO notify participant TINs about non-ACO patients who are in need of interventions in light of the Stark law?

Because quality measure data will now include all patients who receive care from a participating TIN, it is very likely that the performance score attributed to an ACO will include variations in care delivery and achievement of outcomes that are due to patient access to care, insurance coverage, and/or medical complexity. For example, many ACOs have relationships with Federally Qualified Health Centers (FQHCs) to provide care to their assigned beneficiaries. FQHCs provide care to a broader population that may or may not have access to the same services and interventions provided by the ACO and often to individuals with multiple risk factors such as food insecurity, housing instability, or medical complexity. As a result,

performance on the quality measures could be skewed based on inequities and differences in patient mix. This misrepresentation does not serve to drive change in a meaningful and useful way and would penalize ACOs and ACO participant TINs treating more vulnerable populations.

As a result of these many concerns and the potential impact to data integrity, we believe that the expansion to all-payer data for ACOs is inappropriate. This change dramatically increases the complexity of the program, which is not in the best interest of Medicare beneficiaries, CMS or ACOs. Further, the resulting quality performance scores will not represent the quality of care provided by an ACO and will also hamper CMS's ability to evaluate the impact of ACO interventions on quality of care for the patients they serve, which is a critical component of understanding the total value the ACO model provides beyond just reducing costs.

# Recommendation 3: Lower the data completeness requirements beginning at 40 percent with a gradual increase to a maximum of 50 percent for those reporting eCQMs or MIPS CQMs or explore alternative approaches.

Shifting to eCQMs and MIPS CQMs across all payers exponentially increases the volume of individuals for whom data would need to be extracted and aggregated, particularly with the number of beneficiaries assigned to some ACOs. For example, at a minimum an MSSP ACO must have 5,000 assigned beneficiaries, but many ACOs are much larger, some having upwards of 100,000 assigned beneficiaries. Under the new rules, ACOs will have to report on 70 percent of patients, not just Medicare assigned beneficiaries but on all patients across all payers. The magnitude of this increase is startling compared to the small sample required under the Web Interface, requiring significant time and effort to collect the quality data needed for measurement. This new requirement is vastly different than the sampling approach used for Web Interface reporting, which was more feasible and manageable to implement and maintain. ACOs have developed processes and procedures to collect and report the Web Interface data and many must start over again to begin to collect data based on the new requirements.

Due to the challenges related to all-payer data and the potential volume of patients on which ACOs would need to report, we request CMS lower the data completeness level to no more than 40 percent with a gradual increase to a maximum of 50 percent for those reporting eCQMs or MIPS CQMs. Alternatively, CMS should explore the sampling approaches used in the Medicare Advantage program or by the National Committee for Quality Assurance or The Joint Commission. Using an alternative approach of sampling would expand the number of patients on which data are collected compared to the Web Interface but would be more feasible and not as burdensome for ACOs or CMS. Another alternative would be for CMS to consider a policy that would use a minimum attainment standard that requires 50 percent of the quality measures to meet or exceed the 40<sup>th</sup> percentile. This approach would ensure that ACOs perform well on a substantial set of measures to earn savings but does not punish ACOs that miss the mark on a measure that is either not as relevant to their patient population or has a very narrow range of performance rates.

## Recommendation 4: Reassess the appropriateness of the measures included in the APP measure set and solicit additional input through the MAP prior to finalizing a complete set of patient-centered measures for reporting.

CMS significantly changed the quality measure set on which ACOs must report without adequate input from key stakeholders such as the MAP. While a decrease in measures is generally supported and may

reduce reporting burden, we believe the current set is too narrow and not patient-centered. Specifically, the new required measures are narrowly focused on a small set of mostly primary care services.

In addition, because the number of patients to whom the measures would apply has increased exponentially and many of the measures are broadly specified, patients who receive care from a specialist participating with an ACO will be attributed as eligible for a measure denominator for a clinical service intervention that is outside of the typical scope and practice of that clinician. Certain specialists may consider it clinically inappropriate for them to take steps to meet the primary care quality measure if the measure and its related care are outside of their professional focus. For example, if an ACO-assigned beneficiary has an annual skin exam and a diagnosis of diabetes is also captured in the medical record, then MIPS#001, Diabetes: Hemoglobin A1c (HbA1c) Poor Control will be attributed to the dermatologist, and the ACO will be required to include this visit in the measure denominator regardless of whether the HbA1c control is outside of the focus of the visit or purview of the dermatologist. This creates the potential that performance will not be met and ACO quality scores would be negatively impacted. Requiring specialists to collect additional data and/or provide additional services outside of their usual work could also serve as a distraction and negatively impact care delivery.

This concern increases significantly with the all-payer requirement since it will be extremely challenging, if not impossible due to data availability and potential violations of the Stark or HIPAA laws, for ACOs to track patients and their care when they have no direct relationship to the ACO. These concerns are leading some ACOs consider dropping certain TINs from their ACO, while at the same time certain TINs may choose to leave the ACO to avoid burdensome new quality reporting requirements. Either way, this unintended consequence of reducing the breadth of providers engaged in a total cost of care model is troubling.

We urge CMS to re-assess the current measure set and gather more stakeholder input, such as through a Request for Information (RFI) or open stakeholder forum as well as seek feedback from the MAP. The statutory intent of the MAP was to evaluate quality measures to ensure the measures appropriately fit a program, and the MAP did not review these proposed changes prior to the set's implementation.

## Recommendation 5: Clarify/establish quality performance benchmarks in advance for all ACO reporting options.

We continue to believe that using the MIPS quality performance benchmarks to evaluate ACO performance is inappropriate. Further, benchmarks must be set in advance of the reporting year. The previous benchmarking process ensured that ACO quality was evaluated appropriately (e.g., Medicare to Medicare) and reflected their work to improve patient care. The new requirements will evaluate performance scores of individual clinicians, groups, and ACOs as combined and will result in "apples-to-oranges" comparisons as a result. Our example on FHQCs above highlights how the expansion of individuals beyond those assigned to an ACO will change performance scores – not based on an ACO's ability to drive improvement but rather due to differences in access, insurance coverage, medical complexity and other factors.

In addition, ACOs actively track and evaluate their performance on individual measures throughout the reporting year to ensure that Medicare beneficiaries are receiving the appropriate, evidence-based care and to achieve the highest performance scores possible. Because the MIPS benchmarks are subject to change throughout the reporting year (e.g., a second version of the 2021 benchmarks were posted on March 18, 2021 with several benchmarks removed) or not available until well after the reporting year, as is

the case with the administrative claims measures, it is incredibly challenging if not impossible for ACOs to track and evaluate their quality of care while also meeting or exceeding the minimum attainment standard for each measure. ACOs invest significant resources to participate in the model and should be able to understand the metrics they will be scored on in advance, so they can target their resources appropriately.

### Recommendation 6: Retain pay-for-reporting when measures are newly introduced or modified.

We believe that CMS should reverse removing the pay-for-reporting year for measures that are new or with significant changes. Providing the pay-for-reporting year is critical to an ACO's success as it allows an ACO to evaluate their current workflows, data capture processes, and other operational strategies to see where changes are needed and what areas require focus when a measure undergoes significant changes. Further, providing a newly introduced measure or a measure undergoing significant changes with a pay-for-reporting year ensures there are no unintended consequences or flaws in the measure specifications before holding an ACO accountable for performance on the measure. Allowing this time to assess workflows and operations before ACOs are held accountable for performance on measures allows ACOs to be successful in getting credit for the good quality improvement work they are already engaged in, as often times a measure is not only assessing true quality but also how the quality data are captured.

### Conclusion

ACOs remain committed to providing the highest quality care and improving patient outcomes while also delivering this care in the most cost-efficient manner. To that end, we urge CMS to reconsider the decisions finalized in December 2020 and work with our organizations and ACOs to find alternative approaches and a different timeline that will meet CMS and ACO needs. We appreciate your consideration of these recommendations and welcome an opportunity to work with the agency to provide further feedback and to support ACOs and the transition to value.

Sincerely,

American Academy of Family Physicians American College of Physicians American Hospital Association American Medical Association AMGA America's Essential Hospitals America's Physician Groups Association of American Medical Colleges Federation of American Hospitals Medical Group Management Association National Association of ACOs