AMGA
Advancing High Performance Health

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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma:

On behalf of AMGA, I appreciate the opportunity to comment on the interim final rule with comment period (IFC) titled *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* [CMS-1744-IFC]. Outside of the initial waivers that the Centers for Medicare & Medicaid Services (CMS) issued, this April 6 rule represents the first regulatory response to the novel coronavirus (COVID-19) public health emergency (PHE). Subsequent to publication of this rule, CMS issued a second interim final rule with comment period on May 8 titled *Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID– 19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program* [CMS-5531-IFC] that updated CMS-1744-IFC. AMGA is pleased to offer comments on these rules, and we will provide additional insights on CMS-5531-IFC and how these rules are affecting the operations of our members at the appropriate time.

Founded in 1950, AMGA represents more than 440 multispecialty medical groups and integrated delivery systems, representing about 175,000 physicians who care for one in three Americans. Our member medical groups work diligently to provide high-quality, cost-effective, patient-centered medical.

The COVID-19 PHE has impacted various aspects of our nation's healthcare delivery system. AMGA members are on the front lines of this pandemic. Not only are they treating those who have contracted the disease, they have worked to keep their other patients safe at home by cancelling elective procedures and shifting care to telehealth to the extent possible. As a result, there have been significant ramifications for our members, both in their finances and their care delivery models. AMGA appreciates CMS' various waivers and regulatory changes that have allowed our member groups to continue to serve patients in their communities. For example, the expansion of telehealth, reimbursement for telephone codes, and other policy changes have helped our member groups continue to reach and connect with patients and provide the valuable care that is still needed in the midst of the PHE.

We are pleased to offer the following recommendations on the IFC.

Key Recommendations:

Telehealth

- AMGA supports CMS' revision of the telehealth requirements so that smartphones may be used facilitate a telehealth visit. CMS should continue to allow the use of such devices even after the end of the PHE.
- AMGA supports the addition of about 80 codes to the Medicare telehealth list and the modification in how additional codes may be added through the sub-regulatory process.
- AMGA recommends that CMS move to keep this expansion in place beyond the duration of the PHE.

Audio-Only Calls

- AMGA supports the establishment of separate payments for audio-only telephone evaluation and management (E/M) services and the subsequent increase in their relative value units (RVUs) to provide payment parity.
- AMGA recommends that CMS allow audio-only telephone calls to satisfy the face-to-face requirement for collecting diagnosis information for risk adjustment and care coordination purposes.

Medicare Shared Savings Program

- AMGA agrees with CMS' decision to apply the Medicare Shared Savings Program (MSSP) Extreme and Uncontrollable Circumstances policy to all Accountable Care Organizations (ACOs) and to remove expenditures for months that include COVID-19 episodes linked to an inpatient COVID-19 diagnosis. CMS should expand this to include all COVID-19 diagnoses, even if they do not result in an inpatient stay.
- AMGA agrees with providing ACOs in the BASIC glide path with an option to stay at their current level for performance year 2021. However, AMGA recommends that CMS revise its policy that would require an ACO to skip a level and move into a more advanced level for performance year 2022. An ACO should not be required, for example, to advance from Level B to Level D.
- AMGA disagrees with the decision to cancel the 2021 application period. CMS should allow those providers who wish to enter the MSSP to do so.
- AMGA will provide additional comments on the changes to the MSSP in our response to CMS-5531-IFC.

Innovation Center Models

- AMGA continues to support the movement to value-based care. To that end, CMS should provide guidance on the status of the Next Generation (NextGen) ACO program and the Direct Contracting (DC) model.

Comments:

Payment for Medicare Telehealth Services under Section 1834(m) of the Act
AMGA members, along with the larger healthcare system, have retooled their care delivery models in response to the COVID-19 pandemic. In addition to cancelling elective procedures, AMGA members quickly shifted care, to the extent possible, to telehealth. AMGA appreciates the flexibility that CMS has provided, both through the 1135 waiver process and through two interim final rules. While linked to the current PHE, the changes CMS has implemented fundamentally have shifted how patients interact with their providers. Moving forward, the regulatory framework governing telehealth needs to acknowledge this new reality. It will be neither realistic to expect patients to return the previous model nor an appropriate use of resources for providers to attempt to reinstitute previous care practices. Simply stated: the train has left the station. Patients quickly adapted to using telehealth to access care, and there will be some situations where patients will be resistant to return to in-person visits due to the health status of the individual patient, resources available to the patient to get them to an in-person visit, and the nature of the issues that need to be addressed during the visit. It has been demonstrated some circumstances where quality care can be provided virtually. CMS' regulations and payments for telehealth need to reflect this new reality, and attempting to reinstitute earlier restrictions would cause significant disruption. This includes a permanent expansion of the 1135 waivers that allows patient homes to qualify as the originating site and Rural Health Clinics to qualify as distant sites.

AMGA appreciates that Congressional action is needed for CMS to make permanent changes in telehealth policy. However, CMS also should review its authority and enact regulatory changes to the extent possible. CMS support for permanently modernizing the underlying statute also would help efforts in Congress to improve telehealth policy.

Clarifying Telehealth Technology Requirements
CMS has updated its regulatory language at §410.78(a)(3) to add an exception to the definition of "interactive telecommunications system" so that "mobile computing devices that include audio and video real-time interactive capabilities" may be used for telehealth services for the duration of the COVID-19 emergency. Effectively, this revised definition, along with the Department of Health and Human Services (HHS) Office of Civil Rights' enforcement discretion for providers who serve patients in good faith through everyday communications technologies, will allow patients to use smartphones with technologies such as FaceTime or Skype to have a real-time interaction with their clinician. AMGA supports the expanded use of this technology. Patients and providers have found it to be a convenient and safe way to address healthcare needs. In addition, because of the necessity to keep their patients and staff safe, AMGA members have modified their care delivery practices to deliver care with this technology. This need will not change after the expiration of the PHE. CMS should revise the regulatory framework surrounding this technology so patients can continue to access care via their smartphones after the expiration of the PHE.

Additions to the Telehealth List
The interim final rule adds 80 codes to the telehealth list on a Category 2 basis for the duration of the PHE. AGMA appreciates the expansion of the list and recommends that CMS add these codes to the telehealth list on a permeant basis.

Telephone Evaluation and Management (E/M) Services
The rule finalized on an interim basis separate payment for audio-only telephone calls for evaluation and management purposes. AMGA appreciates the steps that CMS took to expand coverage for these services. In addition, in subsequent rulemaking, CMS responded to AMGA's concerns about the significant difference between the RVUs for the audio-only codes and the codes for the comparable telehealth (audio *and* visual) and in-person services by increasing the RVUs for the audio-only codes. AGMA is pleased that CMS addressed the payment differential for the audio-only codes, as many patients are unable to connect via telecommunication technologies. As AMGA members have worked to deliver care to their patients who are remaining in their homes, it has become clear that many patients do not have access to the devices or the broadband services necessary to receive care through video-based technology, such as a smartphone. For some patients, the choice is between an audio-only telephone call and no visit at all. In recognition of the importance of these audio-only visits, AMGA recommends that CMS allow these telephone calls to satisfy the face-to-face requirement for collecting diagnosis information for risk adjustment and care coordination purposes.

Patient history is the main component for establishing a diagnosis, particularly for established patients. Providers are able to use patient history along with a review of previous charted information to inform the diagnosis, often without the need for a physical exam. This is especially true for patients with chronic diseases who can be monitored via audio-only calls, with support from laboratory and vital signs that are commonly taken in the home and can be reported by the patient. Current CMS coding guidelines, which have been in place for more than two decades, require only two components for established patients to be documented among history, examination, and complexity of medical decision making. For those patients who can be accurately diagnosed based on their history, the video component does not provide any extra insight for the provider and is not required per CMS' own coding guidelines for the evaluation and management of the patient. If additional information is needed, patients likely will need to be seen in-person, regardless of whether there was video component to the visit.

Medicare Shared Savings Program
CMS addressed changes to the MSSP in two separate interim final rules. In the interim final rule titled *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency,* CMS addressed changes to the Extreme and Uncontrollable Circumstances Policy for MSSP ACOs. In a subsequent Interim final rule titled *Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program*, CMS addressed other aspects of the MSSP that have been impacted by the COVID-19 PHE. AMGA is appreciative of CMS' attention to issues that influence providers' ability to continue the transition to value-based payment models in midst of the PHE. While we understand that comments on the subsequent IFC are due in July, we believe there are changes that CMS proposed in this interim final rule that require immediate attention.

In the second interim final rule (CMS-5531-IFC) published on May 8, the agency states that it is "forgoing the application cycle for a January 1, 2021 start date." While AMGA acknowledges that CMS is making this change in order to allow current MSSP ACOs to focus on treating patients during the pandemic, we disagree with CMS' approach and urge the agency to allow new

entrants to the program in 2021. The MSSP ACO program is a voluntary model, therefore only those who believe they are ready to move into this payment model will choose to participate. Depriving these groups of the choice to participate in the MSSP in performance year 2021 delays their ability to learn how to deliver care in a value-based model. Additionally, we are concerned about what the impact of forgoing an entire cohort of new ACOs will have on the viability and strength of the program. We urge CMS to allow new ACO applications in 2021.

The May 8 interim final rule allows BASIC track ACOs to elect to remain in their current participation track for one additional year but skip a level the following year, meaning an ACO that is currently participating in BASIC Level B in 2020 can remain at this level for performance year 2021 but must advance to Level D for performance year 2022. While we thank CMS for the giving ACOs the ability to remain at their current level for an additional year, AMGA opposes the policy that would have ACOs advance to the level of the participation in which it would have participated during performance year 2022 had it automatically advanced in performance year 2021.

We do not believe that the MSSP should push groups into a higher risk level after they held steady in 2021. Because groups have had to divert resources to address the COVID-19 pandemic, these providers have not had adequate time and experience in risk-based arrangements. This is particularly concerning for Level B participants that would advance to Level D, which features a higher lost-sharing limit than level C. These groups need extra time to learn how to operate in these arrangements and allowing them to progress through to the next level they would have participated in after deferring allows that.

Addressing quality measurement for the 2020 performance period is also important for ACO participants, and AMGA is pleased that CMS has acknowledged how COVID-19 might skew quality results. AMGA recommends that quality measures for performance year 2020 be pay-for-reporting. We contend that some measures will be difficult to satisfy if patients are not engaging with their providers in office or via telehealth, which is likely due to the current pandemic. Additionally, the restriction on elective procedures may impact or make it difficult for patients to get their breast cancer, colon cancer and other various screenings. This problem could get worse if we see a resurgence of COVID-19 in the fall.

In the interim final rule, CMS includes services provided virtually, through telehealth, virtual check-in, e-visit, or telephone in the definition of primary care services used in the beneficiary assignment methodology. While we recognize CMS' position that including these services in the definition of primary care will "further allow for the continuity and coordination of care," AMGA's members are concerned about the unforeseen consequences of this expanded definition. We believe this revision can create issues in areas of the country where few providers are offering telehealth services. Some practices currently are attracting new patients due to CMS' expansion of payment for telehealth services. AMGA's members are concerned with the unintended consequences of having a patient attributed to their ACO through a telehealth visit and subsequently becoming responsible for the cost and quality of care of that patient, who may not continue to see that practice's physicians once the pandemic ends. We urge CMS to monitor and consider the unanticipated impact of this revision.

Benchmarking and Regional Adjustments

We appreciate CMS' attention to the impact of COVID-19 expenses on MSSP expenditure and

revenue calculations. However, AMGA remains concerned that the impact of COVID-19 healthcare utilization will not be uniform nationally. With increased costs associated with COVID-19 areas in some regions and deferred care due both to stay-at-home orders and a fear of presenting at a healthcare facility—a fear that may linger for years—CMS should consider taking a longer term view of the expenses and quality of an ACO. Instead of looking at performance over a single year, AMGA would be interested in working with CMS and other stakeholders to develop a benchmarking and financial reconciliation process for ACOs that spans multiple years.

For the short term, however, it is critical for CMS to determine if the regional fee-for-service adjustment that is included in the program is sufficient to account for the variation in spending and utilization across the program that can be traced to COVID-19. While the program's design accounts for variations in regional spending, it is unclear if the model, which includes a limit on the regional adjustment, can account for the wide variation in expenses, divergent practice patterns that have resulted, and the unprecedented change in beneficiary behavior that has occurred. CMS asserts that the retrospective application of the historical benchmark will "reasonably account" for lower utilization of services by non-COVID patients. While this intuitively appears to be the case, it may be that the deferred care results in higher expenses and poorer quality. Under current policy, depending on when an ACO entered the program, its update factor will be based on national growth rates, regional growth rates, or a blend of national and regional growth rates. While a national emergency, COVID-19 also is highly localized. It is critical that CMS evaluate whether the current regional factors in the program are sufficient to account for the situation facing ACOs. Otherwise, despite the protections being designed to prevent such an outcome, the nature of the pandemic will render them less effective than intended.

Specifically, CMS should evaluate whether the 5% cap of the regional adjustment is sufficient or needs to be increased.

Innovation Center Models

CMS in the interim final rule addresses changes to two Center for Medicare and Medicaid Innovation (CMMI) models, the Medicare Diabetes Prevention Program and the Comprehensive Care for Joint Replacement (CJR) Model. These policy changes seek to provide participants and beneficiaries with flexibility and continued access in light of the COVID-19 PHE.

While AMGA appreciates CMS' attention to these CMMI models, we believe it is necessary that CMS also address the status of the Next Generation (NextGen) ACO model and the Direct Contracting (DC) model. The NextGen ACO model is set to end on December 31, 2020. CMS should immediately provide NextGen participants with information on how the agency plans to address the impact of COVID-19 in this model. Participants in this CMMI demonstration will feel the effects of the PHE on their beneficiary population. Additionally, these organizations have taken steps to divert resources to help address the current PHE. CMS should consider extending the NextGen demonstration performance agreement period.

Additionally, CMS announced the DC model in 2019 under the Primary Cares Initiative. The DC model, according to CMMI, seeks to "provide new opportunities for a variety of different organizations to participate in value-based care arrangements in Medicare FFS." However, performance year 1 is set to begin in 2021, and those interested in participating in the DC model have now diverted resources to address the COVID-19 pandemic. AMGA believes that CMS

should provide more guidance for interested DC model participants on how the current PHE will impact the start of the demonstration.

We thank CMS for consideration of our comments. Should you have questions, please do not hesitate to contact Darryl M. Drevna, AMGA's senior director of regulatory affairs, at 703.838.0033 ext. 339 or at ddrevna@amga.org.

Sincerely,

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AMGA