AMERICAN COLLEGE of CARDIOLOGY

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SUBMITTED ELECTRONICALLY

May 4, 2020

Brad Smith
Deputy Administrator, Innovation & Quality
Director, Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Amy Bassano
Deputy Director, Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Request for CMMI Model Flexibility Due to COVID-19 Pandemic

Dear Director Smith and Deputy Director Bassano:

The American College of Cardiology (ACC) applauds the Centers for Medicare and Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI) for their diligence and flexibility to address the various patient and clinician issues and improve access to care related to the National Public Health Emergency of COVID-19. **Due to the impact of COVID-19 on care delivery, the ACC requests that CMMI issue immediate participant guidance modifying all Innovation Center models, including Bundled Payments for Care Improvement Advanced (BPCI Advanced).**

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

The College is concerned that the clinical and financial impact of the pandemic, combined with future uncertainty, may cause participants to either drop out of voluntary models or assume downside risk for an unanticipated and unprecedented population. Modifications must be made as soon as possible to support continued participation in these programs and maintain the move to value.

While CMS has released initial guidance related to the Medicare Shared Savings Program (MSSP) and Comprehensive Joint Replacement Program (CJR) as part of the interim final rules released on April 6 (CMS-1744-IFC) and March 30 (CMS-5531-IFC), ACC members and stakeholders still need information related to CMMI programs, particularly BPCI Advanced, which has been the most-specialty specific model to date for cardiology. Although the College recognizes that additional information may be forthcoming, we request that CMMI consider the following recommendations and observations as the agency weighs immediate and long-term changes to Innovation Center models impacted by this pandemic.

Apply the BPCI Advanced Natural Disaster Provision Through the 2020 Model Year

In light of the Section 1135 Waiver issued by the Secretary of Health and Human Services and the Major Disaster Declaration issued by FEMA, the ACC recommends that CMMI apply the natural disaster provision included in the BPCI Advanced participant agreement. The College recognizes that the current provision does not take a pandemic into account; however, allowing this provision to cover the current crisis would serve as the most efficient way to modify the program while providing certainty to participants.

Under the natural disaster provision, affected Clinical Episodes with winsorized spending greater than the final target price will be excluded. Affected Clinical Episodes would include episodes across the country with an anchor stay or anchor procedure beginning in the period up to and including 29 days before the 1/20/2020 effective date of the FEMA-designated disaster start date. They would also include episodes up to and including 29 days after the disaster end date. **The College recommends this policy be applied uniformly to all Episode Initiators nationwide and asks CMMI to confirm that the BPCI Advanced Natural Disaster policy will be applied to all episodes initiated as of December 22, 2019; 29 days before the January 20, 2020 effective date of the FEMA-designated disaster start date.**

The ACC recommends that CMMI definitively apply this policy to all episodes within the 2020 model year. Given projections that the COVID-19 pandemic may continue beyond 2020, CMMI should determine whether the policy should be extended into 2021 when Model Year 4 participation agreements are released later this year and continue to assess the landscape on an ongoing basis, making additional program modifications as needed.

The uncertainty of defining a timeline for the COVID-19 crisis continues to be a concern for the ACC. First, while the federal government may lift its current emergency declaration, several states may continue to keep policies in place to slow the spread of the virus at the regional level. Applying the natural disaster provision uniformly to all participants nationwide until the end of the performance year would prevent the

need for CMMI to later modify the program on a regional basis. In addition, while the College greatly hopes that the country does not experience a resurgence in COVID-19 cases later this year, applying the policy now and through the end of the performance period would provide participants with more certainty should another national emergency declaration or further state-level safeguards be issued.

Apply Adjustments to the BPCI Advanced Application Cycle

On April 30, 2020, CMS released provisions related to the Medicare Shared Savings Program (MSSP) to provide the 517 accountable care organizations (ACOs) with more financial stability and predictability during the COVID-19 pandemic. These provisions included making changes to the financial methodology to the program to account for COVID-19 costs. The ACC supports the approach to "allow all ACOs to be treated equitably regardless of the extent to which their patient populations are affected by the pandemic."[1] CMS is forgoing the annual application cycle for 2021 and allowing ACOs whose participation is set to end this year the option to extend for an additional year. ACOs that currently are required to increase their financial risk through the course of their agreement period now have the option to maintain their current risk level for the following year, instead of being advanced into the next risk level.

Given the latest announcement from CMS regarding ACOs, the ACC recommends that CMMI adjust BPCI Advanced policies in a similar fashion to minimize administrative burden and create equitable treatment for all participants. Recognizing that COVID-19 has impacted the entire country, CMMI should ensure that the opportunity to succeed under Innovation Center models remains equitable to all participants regardless of region. CMMI should also allow participants to use 2020 as an opportunity to understand how COVID-19 is impacting their patient population and care delivery. In addition, the College requests that CMMI explore whether the ability to opt-in or opt-out of clinical episodes can be extended through later years of the model.

The College is committed to the continuation of the BPCI Advanced program and understands that the participation agreement window for Model Year 4 is set to open later this year. **The College recommends that CMMI grant administrative flexibility during this process, similar to what has been done for the MSSP.**

Ensure Appropriate Accountability for Target Pricing and Quality Metrics

The ACC strongly supports actions by CMS to provide participant relief in Medicare's hospital quality programs and the Quality Payment Program (QPP). The College commends CMS for recognizing "that quality measure data collection and reporting for services furnished during this time period may not be reflective of their true level of performance on measures such as cost, readmissions and patient experience during this time of emergency and seeks to hold organizations harmless for not submitting data during this period."[2]

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[1] "Trump Administration Issues Second Round of Sweeping Changes to Support the U.S. Healthcare System During COVID," Press Release, last modified Apr 30, 2020, https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid

[2] "CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID-19," Press Release, last modified Mar 22, 2020,

BPCI Advanced and other Innovation Center models utilize quality measures used under the Medicare programs. Given that some hospitals may be forced to spend less time on data tracking and performance improvement efforts during this time, CMMI should evaluate the impact this may have on its programs. **The ACC recommends that CMMI consider a similar voluntary reporting and hold harmless stance on quality performance under CMMI models. However, as the collection of data during this period is important to understand the impact of the pandemic on patient care and outcomes, CMMI should find ways to encourage participants to submit data while recognizing that it may be an administrative burden to some.**

Impact of the COVID-19 Crisis on Cardiology

The ACC is rapidly working with its members and other societies to develop clinical guidance and recommendations on how to best deliver cardiovascular care to patients impacted either by the virus or by practices put in place to mitigate the spread. Much is still unknown about this disease and its potential impact on cardiovascular conditions.

As clinicians continue to adapt to care delivery during this crisis and prepare for the post-COVID-19 era, CMMI models need to adapt in a similar fashion. The College would like to take this opportunity to present preliminary clinical and practice management observations. While these are early and limited, we believe it is important to closely monitor these trends as CMMI considers future programs and modifications.

The ACC encourages CMMI to stay up to date on the latest clinical guidance, frontline observations, and practice management recommendations in the ACC's COVID-19 Hub at www.acc.org/covid19.

Preliminary Clinical Observations and Recommendations - STEMI

The ACC, in partnership with the Society for Cardiovascular Interventions (SCAI) and the American College of Physicians (ACP), issued a consensus statement on the *Management of Acute Myocardial Infarction During the COVID-19 Pandemic*.[3] As noted in the statement, "cardiovascular manifestations of COVID-19 are complex with patients presenting with AMI, myocarditis simulating an ST-elevation MI presentation, stress cardiomyopathy, non-ischemic cardiomyopathy, coronary spasm, or nonspecific myocardial injury."[4]

A preliminary analysis of nine programs showed an estimated 38% reduction in US cardiac catheterization laboratory STEMI activations. While the immediate cause may be due to factors such as misdiagnosis or changes to pharmacological treatment, another cause may be patients avoiding the hospital out of fear or social distancing concerns.[5] While the ACC is actively disseminating patient education to ensure that patients seek care during cardiac events, we remain greatly concerned that care

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https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.

[3] Mahmud E, et al. J Am Coll Cardiol. 2020; doi:10.1016/j.jacc.2020.04.039.http://www.onlinejacc.org/content/accj/early/2020/04/17/j.jacc.2020.04.039.full.pdf.

[4] Mahmud E, et al. J Am Coll Cardiol. 2020; doi:10.1016/j.jacc.2020.04.039. http://www.onlinejacc.org/content/accj/early/2020/04/17/j.jacc.2020.04.039.full.pdf.

[5] Garcia S, et al. J Am Coll Cardiol. 2020;doi:10.1016/j.jacc.2020.04.011. http://www.onlinejacc.org/content/early/2020/04/07/j.jacc.2020.04.011

avoidance may prevent patients from presenting for care, resulting in a population at more advanced stages of disease with a higher risk of mortality.[6]

The ACC's National Cardiovascular Data Registries (NCDR) and many EHR systems have been updated to capture data on patients with confirmed COVID-19 diagnoses. In addition, the NCDR is now tracking patients who may experience a delay in care due to rescheduled procedures or changes in safety protocol. **The ACC anticipates that broad application of the natural disaster policy should result in the exclusion of complex COVID-19 cases from a participant's target pricing. The College recommends that CMMI monitor claims data closely to ensure that participants are not penalized for the care of patients with COVID-19 or those whose care had to be modified to ensure the safety of patients and staff.**

Practice Management Observations and Recommendations

In addition to the clinical impact of the pandemic, the ACC is following the impact on practice management. According to a MedAxiom survey conducted at the end of March, most of the cardiovascular programs noted a 50 to 75 percent rate in rescheduled procedures due to the impact of stay at home orders, staffing safety, and employment changes.[7]

Pre-COVID, cardiologists often reported difficulty meeting the payment/patient volume thresholds needed to qualify as an Advanced Alternative Payment Model (Advanced APM) qualifying participant under the Medicare Quality Payment Program. In order to maintain social distancing and preserve personal protective equipment, the ACC and its members have supported the call to delay elective procedures. **While the good news is that most elective procedures are being rescheduled to a later date and not canceled, the ACC recommends that CMMI monitor episode volume under BPCI Advanced to determine if clinicians are able to meet necessary CMS and CMMI participation thresholds for the 2020 performance year.**

Transformation of Care

While barriers to the broader delivery of telehealth and cardiac rehabilitation services still exist under the fee-for-service Medicare structure, they should be explored as key components of current and future CMMI models.

Thanks to swift changes by CMS and the payer community, the use of telehealth by phone and video has greatly increased which has allowed for vital patient access to care during this pandemic. Remote monitoring of implanted devices has helped to replace in-person routine nursing visits. This recent use of telehealth has allowed cardiac specialists to focus on the physician-patient relationship along with the clinical care they are providing. **Virtual visits have been crucial to the continued delivery of patient care during this crisis.**

Cardiovascular care teams are also working to explore innovative ways to deliver cardiac rehabilitation through home-based, virtual services. The benefit of cardiac rehabilitation for vulnerable patient populations is clear. However, even before COVID-19, patients, particularly those in rural areas, have had

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[6] "Coronavirus Disease 2019," CardioSmart, last modified Apr 28, 2020, https://www.cardiosmart.org/Coronavirus?_ga=2.93627293.1628433187.1587994608-416557445.1572453498.
[7] "SURVEY: IMPACT OF COVID-19 ON CV ORGANIZATIONS," Threats, Opportunities and Insights to Navigate the Pandemic. *MedAxiom*, 2020.

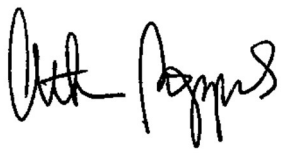
a difficult time accessing cardiac rehabilitation. Post-COVID-19, social distancing, cleaning protocol, and necessary equipment spacing will also impact the volume of patients who are able to go through cardiac rehabilitation at a facility. Many programs are already unable to expand their cardiac rehabilitation centers due to Medicare policies. **While the ACC recognizes that remote cardiac rehabilitation programs have been developed, but are largely untested, the College sees this as an opportunity to work with CMMI to develop an innovative way to improve access to cardiac rehabilitation and improve patient outcomes.**

Conclusion

The ACC greatly appreciates the work of CMS and CMMI to address patient and clinician needs during the COVID-19 crisis. The College is especially appreciative of the efforts to engage frontline clinicians through ongoing stakeholder discussions to inform policy changes.

The College looks forward to coming guidance from CMMI regarding modification to its models, as well as the opportunity to work with the Innovation Center. The College work like to work with you to determine how the experience gleaned from this pandemic can be applied to current or future models to transform the delivery of cardiovascular care. Should you have any questions or like to engage in further discussion, please contact Christine Perez, Director of Payer and Care Delivery Policy at cperez@acc.org or at (202) 375-6630.

Sincerely,



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