



May 13, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS 1744-IFC
PO Box 8016, 7500 Security Boulevard
Baltimore, MD 21244-8016

Submitted electronically: <http://www.regulations.gov>

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

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the steps taken by the Centers for Medicare & Medicaid Services (CMS) in response to the COVID-19 Public Health Emergency (PHE). The American College of Cardiology 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.

Decisions made in the interim final rules with comment periods (IFCs), as published in the Federal Register on May 8 as well as a prior IFC published April 6 are helpful to provide clinicians and facilities with increased flexibility to respond to the COVID-19 PHE. ACC members are particularly heartened by the decision to facilitate remote care of patients through additional telehealth flexibilities and payment adjustments.

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Cardiologists and cardiovascular care teams quickly worked to incorporate these changes into workflows to care for patients.

Based on initial experience navigating the new regulations, the ACC is providing feedback on aspects of the IFC that could be clarified or expanded, as well as topics for consideration in future rulemaking or subregulatory guidance. Areas where additional activity/information would be particularly helpful include provision of additional cardiovascular services from a distance, alterations to the Quality Payment Program (QPP), and planning for a gradual return to more normal care protocols.

Flexibility for Remote and Telehealth Services

The ACC applauds CMS for taking significant action to enhance the ability of the healthcare workforce to focus on COVID-19 treatment and relief by providing telehealth flexibilities throughout the duration of the PHE. Changes to telehealth originating site requirements and frequency limitations have allowed patients to continue receiving care while social distancing and preserving personal protective equipment. Allowing provision of these and other remote communications technology services to new patients and with greater supervision flexibility also furthers those aims. Enforcement discretion to allow use of everyday communications technology and to allow reduced or waived copays has also proven important. Waiving requirements that clinicians be licensed in the state where in-person or telehealth services are rendered if other criteria are met creates the ability for the workforce to muster and enhance access to care where needed. Finally, payment parity for telephone-only services recognizes both the significant amount of time and complexity many patients warrant as well as many elderly or disadvantaged patients' inability to access care through a system that utilizes a video portal.

Remote Cardiac and Pulmonary Rehabilitation Services

Cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) are medically directed and supervised programs designed to improve a patient's physical, psychological, and social functioning. While CMS has allowed outpatient E&M services to be reimbursed for remote home visits, this flexibility does not currently extend to CR/PR services. These programs utilize supervised exercise, risk factor modification, education, counseling, behavioral modification, psychosocial assessment and outcomes assessment. Some private payors currently have programs in place to promote telehealth for cardiac and pulmonary rehabilitation with good health effects and outcomes. However, as many programs have chosen to halt their face-to-face CR/PR interactions to comply with social

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distancing amidst the COVID-19 public health emergency, the suspension of these services has significant implications for both patients and programs. There are many reasons why a similar approach for CR/PR services is needed:

1. Patients with cardiovascular and/or pulmonary diseases derive significant health benefits, including reduced hospital readmission rates, when they participate in cardiac/pulmonary rehabilitation. These patients are at increased risk of mortality as well as adverse cardiovascular and pulmonary disease-related events if they are unable to participate in a supervised program of CR/PR while at home.
2. Such events could result in increased mortality but also increased need for emergency department visits or hospitalizations which would increase patients' exposure to COVID-19 and its associated complications, increase their risk of decompensation of their underlying cardiac or pulmonary disease, and occupy acute care beds needed for patients with COVID-19.
3. Regular contact with CR/PR professionals would help to address behavioral and psychosocial aspects of these patients' care during the COVID-19 pandemic such as nutritional choices, access to food, smoking and alcohol consumption, mental health concerns, stress management techniques, and medication adherence. These factors are not only important to the long-term health of our patients but are particularly critical now to support them during this unprecedented crisis.
4. The inability to provide for reimbursable CR/PR services during the COVID-19 pandemic will likely result in layoffs of our CR/PR professionals and jeopardize the viability of some, if not many, CR/PR programs, exacerbating an already significant problem with lack of access to CR/PR programs in many parts of the United States.

The ACC recommends CMS add cardiac and pulmonary rehabilitation services to the Medicare telehealth list using the newly defined subregulatory process described in the May 8 IFC. The College believes such a change would also be aligned with efforts taking place in other parts of the government, such as the Agency for Healthcare Research and Quality (AHRQ) TAKEheart Initiative that aims to increase utilization of cardiac rehabilitation services to improve outcomes. TAKEheart has been coordinating with sites to share resources and strategies to support CR patients during the pandemic.

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Medium-term Flexibility

It is likely that the course of the COVID-19 crisis will vary significantly in onset and duration in different states and regions. While the danger may be deemed to have passed in some geographic areas—and possibly even nationally—social distancing and other measures will be necessary in other areas to navigate prolonged or delayed outbreaks, particularly while proven therapies for COVID-19 remain unavailable. Continued flexibility for telehealth services and other essential waivers will be needed if the PHE ends while *any* COVID-19 cases remain.

Further, even as the pandemic begins to subside, an immediate return to the traditional face-to-face model of patient care will not occur, as communities and patients face ongoing limitations and even reluctance to return to normalcy. It will be necessary for newly enacted telehealth flexibilities to continue for some time. **The ACC encourages CMS to consider additional changes that would allow telehealth and licensing flexibility on an enduring basis as a tactic to respond to the PHE and mitigate risk after surges until vaccines or other treatments are available.** If statutory limitations inhibit further flexibility, it would be important to have that clarified for the public and Congress so further changes can be made.

One way to convey this commitment would be to include telephone management CPT codes 99441-99443 as active, paid services—carrying over the work and technical inputs already deployed in this interim final rule—in CY 2021 physician fee schedule rulemaking. This would provide a period of stability and could be revisited in CY 2022 rulemaking or informed by subsequent changes that Congress may execute. It would also allow for the possibility that the CPT Editorial Panel or AMA RUC may revisit code descriptors or payment inputs in the coming months.

Quality Payment Program (QPP)

Merit-based Incentive Payment System (MIPS)

The ACC appreciates CMS's application of the MIPS extreme and uncontrollable circumstances policy to MIPS eligible clinicians and groups for the 2019 performance year. The extended data submission deadline and ability to reweight the MIPS categories to zero percent allowed clinicians to prioritize their focus on patient care.

While the College is pleased with this action, many clinicians and groups who are now experienced with the QPP process were able to submit complete 2019 performance year data before the original March deadline. CMS acknowledges that due to an

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increase in the number of QPP participants receiving a neutral payment adjustment under the extreme and uncontrollable circumstances policy, it is likely that anyone who qualifies for a positive payment adjustment will receive a lower than expected amount. **The ACC recognizes that CMS is constrained by the requirement to ensure budget neutrality; however, we encourage CMS to continue exploring ways to balance the need for flexibility with the ability to provide meaningful incentives to those clinicians who remain committed to QPP participation.**

The ACC anticipates that the COVID-19 PHE will have a greater impact on 2020 QPP performance. Whether due to the clinical effects of COVID-19 in patients or practice changes implemented to mitigate the spread of the disease, it is likely that quality and cost metrics will be impacted. Much is still unknown about the clinical impact of this crisis. **CMS should determine how to fairly benchmark 2020 QPP performance and evaluate how this performance year may impact the benchmarks used for the 2021 performance year.**

Advanced Alternative Payment Models (Advanced APMs)

Pre-COVID, cardiologists often reported difficulty meeting the payment/patient volume thresholds needed to qualify as an Advanced APM qualifying participant under the QPP. In order to maintain social distancing and preserve personal protective equipment, the ACC and its members have supported the call to delay elective procedures. The good news is that most elective procedures are being rescheduled to a later date and not being canceled; however, this may impact 2020 performance year volume especially if cases that would have been scheduled at the end of this year are moved to early 2021.

The ACC recommends that CMS and CMMI monitor episode volume under models such as Bundled Payments for Care Improvement Advanced (BPCI Advanced) to determine if clinicians can meet necessary Advanced APM participation thresholds for the 2020 performance year. While the College recognizes that the payment and patient thresholds are set in statute, we ask that CMS and CMMI explore whether program-level changes to elements such as attribution methodologies can help cardiologists qualify as Advanced APM participants.

As it remains unclear when the clinical and financial impacts of the COVID-19 PHE will end, the ACC encourages CMS to continue reviewing the QPP to determine if further flexibility is needed for the 2020 performance year and future years of the program.

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Center for Medicare and Medicaid Innovation (CMMI) Models

The ACC was pleased to see guidance on the Medicare Shared Savings Program (MSSP) and Comprehensive Joint Replacement (CJR) program in the two interim final rules. The College supports the focus to reduce administrative burden and ensure equitable performance for those participating in these models and recommends that a similar approach be applied to all CMMI models. CMS must prioritize support to participants in Innovation Center models to ensure that clinicians continue to play a role in the move to value.

Medicare Shared Savings Program (MSSP)

With regard to the MSSP changes, the ACC supports the ability for all PY 2020 participants to elect the Basic Track Level B risk levels: 0% downside risk and up to 40% shared savings. Many clinicians are concerned with their ability to assume financial risk during this unprecedented time. This change, along with existing disaster provisions in the MSSP, will support participants as they weigh continued participation in the model.

Bundled Payments for Care Improvement Advanced (BPCI Advanced)

Guidance related to other CMMI models such as the BPCI Advanced program was notably absent from both interim final rules issued by CMS. **The ACC has engaged CMMI leadership to request immediate changes and program guidance for BPCI Advanced and other Innovation Center models impacted by the COVID-19 PHE.**

Specific to BPCI Advanced, the ACC has recommended that CMMI apply the existing natural disaster provision to account for the pandemic. Other CMMI models such as the Next Generation ACO already consider an “epidemiological event” as a trigger event for their disaster policies. Under the BPCI policy, 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. Given

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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.

Future Considerations

Accelerated and Advance Payments Program

Using new flexibility from the CARES Act, CMS expanded its program for accelerated/advance payments to improve Medicare providers' short-term financial footing and ensure continued access to necessary resources to sustain their practices. This funding can help practices meet commitments, but clinicians are increasingly concerned that the payoff terms may only defer financial shortfalls should clinical care workflows not normalize sufficiently in the coming months.

Currently repayment begins through reduction of future payments after 120 days and must be complete before 210 days post-disbursement under the program. Any amount outstanding at that time will be subject to regular procedures for interest rates applying to overpayments. The rate for such an overpayment secured by April 19, 2020 is 10.25%. As the impact of the COVID-19 PHE appears increasingly likely to extend beyond the 210-day window, and patient workflows appear unlikely to return to anything resembling normal volumes during that span, **the ACC recommends CMS extend the interest-free repayment period and reduce the applicable overpayment interest rate for the Program for payments made as a bridge during the PHE.** Extending the repayment window to two years and lowering the rate to 1%, similar to the Paycheck Protection Program, would provide a greater degree of certainty for clinicians, though even that timeframe may need to be extended.

Enhanced Practice Expense Costs

As mentioned earlier during discussion of the need for telehealth flexibility to extend for some period after the COVID-19 PHE, an immediate return to the traditional face-to-face model of patient care will not occur. Communities and patients will face ongoing limitations and some reluctance to return to normalcy. When patients begin returning to offices for services, imaging, and minor procedures, enhanced protocols will be deployed to prevent COVID-19 spread and maintain public confidence in the safety of the health care system. In fact, this is happening right now for services deemed essential that are provided to patients with ailments that cannot be delayed. Additional gloves,

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masks, and cleaning supplies are being used to provide services—essentially all services—that would not normally require them. Clinical staff devote increased amounts of time to clean rooms and surfaces. **The ACC recommends CMS incorporate some amount of enhanced practice expense to every patient visit to account for these enhanced costs.** This could be done by increasing the payment for every patient visit by the amount of some direct practice expense input as a proxy, since these precautions will be taken with every patient for the foreseeable future. One proxy candidate would be minimum multi-specialty visit pack SA047 that includes additional non-sterile gloves and other disposable supplies, and doubling the normal cleaning time included in an office visit.

Volume Requirements in National Coverage Determinations (NCDs)

A number of cardiovascular NCDs include minimum volume requirements used as surrogates to demonstrate the necessary infrastructure and faculty with relevant procedures/technology. Many of these procedures have been deferred to preserve inpatient space and personal PPE. It is unlikely all of the pent-up demand will be met in a timeframe that allows sites that would have otherwise qualified to maintain the requisite volumes to meet coverage criteria. **It would be helpful for CMS to convey some degree of flexibility regarding these standards through an upcoming, additional interim final rule or subregulatory guidance.** One approach could be to use prior years' volume data for longstanding (two years of experience) sites, while giving newer sites an additional year to meet average/minimum thresholds. Another would be to reduce or waive requirements during the PHE.

Prior Authorization

Per recommendations from CMS, non-emergent elective procedures are now being postponed or performed primarily in the outpatient setting. Only the most serious procedures are being considered at inpatient facilities. As these inpatient settings are increasingly crowded with patients fighting the COVID-19 virus, patients awaiting life-saving procedures are not only at a higher risk of infection but are also taking up valuable ICU bed space. Removing barriers to patients receiving their procedures and treatment in an expeditious fashion is more important now than ever before. In addition, many practices must devote significant resources complying with prior authorization requirements, which utilizes valuable and scarce clinician bandwidth and foments inefficiency.

These administrative burdens could be ameliorated by instructing Medicare Advantage plans to waive prior authorization requirements throughout the duration of the national

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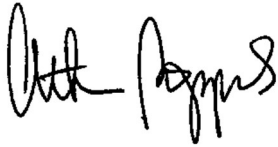
emergency and for a period of time after the emergency is lifted. As elective procedures are re-scheduled nationwide, we are concerned that patients and cardiovascular clinicians will experience a backlog in the prior authorization process. **CMS should consider extending any waivers beyond the emergency period to ensure an efficient return to patient care.**

Appropriate Use Criteria (AUC) Program

The AUC program is currently in a voluntary education and testing period through the end of 2020. The mandatory program is set to begin on January 1, 2021. Many hospitals and cardiology practices had intended to use this year to implement clinical decision support mechanisms (CDSMs) and update their workflows to comply with the requirements of the mandate. **Given the need to focus resources and energy on changes to patient care and practice management impacted by COVID-19, complete implementation the AUC program should be delayed.**

Thank you for the opportunity to comment on this interim final rule. The ACC appreciates your leadership and flexibility in supporting the response to the COVID-19 pandemic and looks forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact James Vavricek, Director of Regulatory Affairs, at 202-375-6421 or jvavricek@acc.org.

Sincerely,



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