



September 14, 2020

Submitted via www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2021, published on August 3, 2020. 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 52,000 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.

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The proposed rule includes both policy updates and many modifications to individual inputs for physician fee schedule services within the Resource-Based Relative Value Scale (RBRVS) upon which the ACC provides feedback. In this letter the ACC will focus on payment policy and technical changes that drive payment for individual services, in hopes of giving CMS staff adequate time to incorporate revisions into the fee schedule, after the proposed rule was published much later than normal. This letter also addresses other programmatic issues related to the Quality Payment Program, MIPS Value Pathways, Alternative Payment Model Performance Pathway, and more. This letter includes significant comments on:

- Payment for evaluation & management (E/M) services;
- Medicare telehealth services, including those provided during the Public Health Emergency (PHE);
- Valuation of specific services related to atrial septostomy, pacing heart stimulation, intracardiac echocardiography, and ventricular assist device (VAD) interrogation, among others;
- Practice Expense (PE) refinements;
- Scope of Practice and Related Issues;
- Quality Payment Program (QPP) updates;
- Medicaid Promoting Interoperability Program Requirement for Eligible Professionals;
- Cardiology specialty measure set;
- Qualified Clinical Data Registries (QCDRs);
- Advanced Alternative Payment Models (Advanced APMs);
- Medicare Shared Savings Program (MSSP); and
- MIPS Value Pathways (MVPs) & Alternative Payment Model Performance Pathway (APP).

Evaluation and Management (E/M) Services

Budget Neutrality

After proposing and revising changes to E/M documentation and payment in 2019 and 2020 rulemaking, the proposed 2021 rule includes final policies and rates for these services that will take effect in 2021. The ACC supports Agency plans to utilize the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel coding framework and AMA Specialty Society Relative Value Scale Update Committee (RUC) recommended values for office and outpatient visits starting January 1, 2021. The framework was the result of significant collaboration by many stakeholders. CMS' new office visit policy will lead to significant administrative burden reduction and better describe and recognize the resources involved in office visits as they are performed today.

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The ACC also appreciates the actions taken by various agencies to provide flexibility, regulatory relief, and financial assistance to physicians and health care professionals to meet the needs of patients during the COVID-19 pandemic. As a result of confronting the novel coronavirus in hard-hit communities and mitigating its spread throughout the country, many practices face a myriad of economic hardships. Members fear the financial instability created by this public health crisis will be exacerbated by budget neutrality adjustments required when CMS implements the widely supported Medicare office visit payment policy finalized for 2021. **Therefore, the ACC strongly urges CMS to utilize its authority under the public health emergency (PHE) declaration to preserve patient access to care and mitigate financial distress due to the pandemic by implementing the office visit increases as planned while waiving budget neutrality requirements for the new Medicare office visit payment policy.** In these extraordinary times, such a response is appropriate to maintain the viability of practices and access to care.

Budget neutrality cuts of this magnitude will impose significant hardship on many physicians and health care professionals who do not report many office visits. The budget neutrality driven cuts also will reduce the positive impacts of the office visit changes for specialties for whom the office visits are a high proportion of their services.

Payment reductions of this magnitude would be a major problem at any time. The reductions included in this proposed rule under the current extraordinary circumstances, which include steep cuts to many of the specialties that have been on the front lines in efforts to treat patients in the midst of the COVID-19 pandemic, will be devastating. Some physician practices may be able to recoup a portion of that revenue, but not all physicians will be able to do so. While reopening is occurring in phases for many physician practices, certain patients are unable or unwilling to leave home for an in-office service or procedure, and physicians are not be able to see nearly as many patients as they did before COVID-19 due to new safety precautions and personal protective equipment supply. In addition to having reduced capacity due to safety precautions, physicians also face increased expenses post-pandemic due to these same essential safety measures.

In addition, CMS loaned \$40.4 billion as a lifeline to physicians, health care professionals, and other Part B suppliers during the initial phase of the pandemic through the Advanced Payment Program. Under current terms, these loans will be recouped by offsetting Medicare payments beginning in August. Medical societies are seeking regulatory and statutory improvements to these loan repayment terms, including a much lower interest rate. Unfortunately, even in the event of improved terms, many physician practices face the possibility that they will have either just finished repaying these loans or still be in the process of repaying when the budget neutrality cuts take effect, compounding the negative impact.

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These challenges highlight the urgent need for CMS to ensure practices facing severe economic strain and uncertainty can continue meeting the needs of patients during and after the pandemic. If practices are unable to repay, they may fold rather than struggle with more debt in a declining payment environment, worsening the physician shortage worse. **For these reasons, ACC strongly urges CMS to use its authorities and flexibilities under the PHE to implement the office visit increases and waive the requirement for CMS to adjust Medicare physician payments for budget neutrality when it proceeds with the office visit coding and payment changes it has finalized for 2021.**

E/M Time Inputs

CMS proposes to alter the service times it previously finalized for E/M services to reflect the median of each service period and the sum of those medians as a total time. The RUC recommended utilizing the median total time, a path previously adopted by CMS. ACC's understanding of the service time recommendations for E/M services is that a calculated discrepancy exists between the sum of the medians of the pre- intra- and post-service times and the median of the summed total times for some codes. With the relatively large data set of nearly 1200 RUC survey responses for the E/M services, the sum of the medians of the three different time components does not necessarily equal the total time median, the median of the sums. It was felt a sum of medians would be less accurate than the raw survey result of the median total time. **The ACC recommends CMS use the original RUC recommended median of total times.**

Services with Global Service Periods

Surgical specialties participated in the RUC survey and their data often indicated longer time and greater amounts of work than primary care and other specialties. However, CMS proposes not to apply the office visit increases to the visits bundled into global surgery payment. This decision undercuts the concept of relativity within the fee schedule. **The ACC recommends that CMS reconsider this position. Instead, CMS should implement the RUC recommendation to increase the post-operative office visits to retain relativity within the RBRVS.**

This would align with precedents when adjustments were made during the first 5-year review, third 5-year review, and elimination of consultation codes in 2011. Failure to adjust bundled post-operative visits would disrupt relativity in the fee schedule and effectively create specialty payment differentials. The guiding principles of the RUC/CPT Workgroup included a statement redistribution of payments among specialties was not a goal. Not adjusting these services ignores this principle and undermines the manner in which all specialties have worked together to create an environment that gives more significant recognition and balance to non-procedural services. The lack of adjustment by CMS seems a de facto workaround to address questions surrounding values currently assigned to global services.

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Comment Solicitation on GPC1X

CMS proposes to move forward with previously finalized implementation of add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition.

The ACC appreciates CMS' intent to ensure that physicians are adequately paid for those patients that are outliers to the typical patient described in the valuation of office visits. However, the vignettes utilized in the recent RUC survey of E/M services already often describe a patient that would have ongoing primary care services and/or have a single, serious, or complex chronic condition. For example, the vignette for 99215 is *Office visit for an established patient with a chronic illness in a severe exacerbation that poses a threat to life or bodily function or an acute illness/injury that poses a threat to life or bodily function.*

Regardless of service performed, a surgical procedure or an office visit, physicians should have a way to identify outlier patients where additional payment is warranted. The ACC previously recommended CMS not implement GPC1X while the CPT Editorial Panel considered more precise language and usage, as the current definition may allow for it to be added to every E/M visit. Efforts on that front have not yet produced an alternative that fits this purpose, demonstrating the difficulty of capturing resources CMS believes are undercounted in primary care and some specialty visits. The ACC remains uncertain of the description of this service, its applicability to cardiovascular care, and whether it is redundant to updated valuation for E/M codes. Since it seems it could be added to virtually all E/M visits, implementation of this proposed code would compound the impacts of E/M proposals discussed earlier amid the COVID-19 PHE. **For these reasons, the ACC again recommends that CMS postpone the implementation of this add-on code, possibly taking the topic up again in the future after assessing the impacts of E/M payment rate modifications.**

In CY 2021 proposed utilization projections for add-on code GPC1X, CMS assumes the code would be applied to 75% of all office visit claims, costing the Medicare program \$3.3 billion annually. This add-on code alone will account for a 3.5% reduction in the conversion factor. This is an increased prediction from 50% of E/M services in CY 2020 rulemaking to 75% in this proposed rule for CY 2021. CMS states that stakeholders have not submitted specific comments or alternative recommendations on the utilization of this "service", however, CMS' assumptions are not explained and the service itself is not clearly described.

While the ACC continues to think this code should not be deployed in 2021, if CMS does move ahead it should start with a conservative initial utilization estimate for the service. The College's experience is that even with established services that undergo redesign, utilization rarely hits the same threshold as the prior coding system for several years. In the instance of a brand new code with definitional

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problems that will limit use by those leery of future compliance issues, **the ACC suggests it would be appropriate for CMS to estimate GPC1X utilization at 5% of relevant E/M services, or roughly 12.4 million units.** This would more closely parallel the experience of transitional care management services in 2013.

Telehealth and Communications Technology Services

Throughout the COVID-19 PHE, CMS has moved quickly to make changes that enhance the ability of the healthcare workforce to focus on COVID-19 treatment and relief by providing telehealth flexibilities. The ACC applauds CMS for rapidly taking significant steps. 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. In this proposed rule, CMS looks to build on those changes and experiences by proposing or considering changes to continue responding to the PHE or that would endure beyond the PHE. The ACC supports some of those changes and urges caution on others.

Telehealth Services List

After adding many services to the telehealth services list through emergency rulemaking for the duration of the PHE, CMS considered services identified through public requests and internal review for permanent addition to the telehealth services list. CMS proposes the addition of several services to the telehealth service list which are similar to other consultations and office visits that are currently on the telehealth services list (Category 1 services) on a permanent basis. This list of services does not include many services expected to be provided by cardiologists, but the ACC agrees these services make sense to add permanently.

CMS also proposes the creation of a new category of services that may be added to the telehealth services list on a temporary basis (Category 3 services). This category of services would include services added during the PHE for which CMS determined there was likely to be clinical benefit when furnished via telehealth, but for which evidence did not support permanent addition to the list under Category 1 or Category 2 criteria. Nearly all the services emergently added to the telehealth list during the PHE

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would be Category 3 services. Further, CMS proposes several additions to the telehealth service list as Category 3 services for the duration of the PHE. The ACC supports creation of a new category to identify and include services on the telehealth list on a temporary basis as a mechanism to be responsive to the current, and potential future, PHEs.

Finally, CMS proposes that the addition of Category 3 services and various other flexibilities and waivers implemented throughout the PHE in separate emergency rulemaking will last until December 31, 2021 or the end of the calendar year in which the PHE ends, whichever is later. This is a helpful approach and provides a sense of stability to clinicians and practices and facilities, something the ACC sought in prior comments and conversations. Should the impacts of the PHE extend deep into 2021, it will again be helpful for the medical field to be able to plan further than 90 days in the future. For example, if a PHE extension would terminate November 20, 2021 and ultimately is not renewed, a six-week transition path may not make sense across the nation or in some regions depending on local pandemic conditions. **The ACC recommends at least a six-month notice period in advance of terminating the flexibilities and waivers implemented throughout the PHE, in order to provide the medical community sufficient time to make the necessary changes and adjust properly.**

Cardiac and Pulmonary Rehabilitation

A class of services CMS did not propose to add as a Category 3 telehealth services for the duration of the PHE is cardiac and pulmonary rehabilitation. The ACC and other stakeholders previously recommended these services be allowed as telehealth services during the PHE. We highlight them here again for consideration under the new Category 3 construct.

Cardiac and pulmonary rehabilitation services are medically directed and supervised programs designed to improve a patient's physical, psychological, and social functioning. These programs utilize supervised exercise, risk factor modification, education, counseling, behavioral modification, psychosocial assessment, and outcomes assessment. A handful of private payors currently have programs in place to promote telehealth for cardiac and pulmonary rehabilitation with good health effects and outcomes. However, as many face-to-face programs have chosen to suspend their CR/PR programs to comply with social distancing amidst the COVID-19 public health emergency, the suspension of these services has significant implications for both patients and programs.

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.

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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.

Regular contact with cardiac and pulmonary rehabilitation professionals would help to address behavioral and psychosocial aspects of these patients' care during the COVID-19 PHE 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.

For these reasons, **the ACC recommends CMS reconsider the addition of these services under the new construct of Category 3 services.** These services are described by CPT codes 93797, 93798, G0422, G0423, and G0424.

Comment Solicitation on Audio-Only Visits

During the COVID PHE, CMS began paying separately for audio-only telephone E/M services, using existing CPT codes 99441-99443 for increasing periods of time spent on the telephone with a patient. While these services had previously not been covered, CMS found it appropriate to make accommodations as a means of reducing exposure risk during the PHE, and for the many beneficiaries who are somehow limited in their ability to access the audio-visual communication that underpins telehealth E/M services. The ACC highlighted the need for this solution early and often in the PHE and appreciates the leadership CMS showed by taking this approach. **The ACC emphasizes the need for these services particularly in the Medicare patient population, particularly for patients in their 80s or 90s.** Many find audio-visual communication platforms challenging, or inaccessible altogether. Maintaining access can help address health care disparities within our socioeconomically depressed, rural, and senior citizen communities, whose access to smart phone and broadband technology (and comfort level) may be limited.

Looking forward, the Agency indicates it is limited by statute in its ability to waive beyond the PHE the requirement that telehealth services be furnished using technology that includes an audio/video feed. The ACC recognizes that limitation and offers comments from several perspectives. **Whether through CMS action or CPT and RUC activity, the ACC supports creation of a framework that allows for continued coverage and appropriate payment of audio-only telephone services.**

From one perspective, the ACC questions whether it still appropriate for these services to be considered telehealth within the standards of the formal Medicare telehealth program. When CMS

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deemed these services non-covered in CY 2008 rulemaking, it stated it was doing so because they are non-face-to-face and because the code descriptors include the provision of services to parties other than the Medicare beneficiary. (The latter objection seems unnecessary as the services are not provided to other parties, but *through* other parties.) Since that time, non-face-to-face services that do not entail both audio and video have been created and deployed in recent years, such as virtual check-ins and store and forward remote evaluation. The ACC suggests it would be possible for CMS to begin covering the telephone E/M codes under the current remote communications technology/virtual services rubric. Time-based levels that function as approximately E/M levels 2-4 have proven effective during the PHE.

From a different perspective, it may be preferable to start over with new code language and pricing inputs that better reflects current use. This could be undertaken through the CPT and RUC processes, by CMS through creation of a G code, or both. These telephone codes have been used to report services during the PHE that are different from the use envisioned when they were drafted in 2006. During the PHE, clinicians have addressed conditions and scenarios that are more complex than the original valuation recommendations foresaw, potentially calling into questioning the original valuation. Discussions may take more time than allowed in the current code set and may involve review of data from wearable devices. Direct practice expense inputs are likely different than those originally developed as well. Cardiologists who deployed telehealth aggressively describe a significant reliance on clinical staff to execute telephone management in a smooth and effective manner. **Whichever path is pursued, the value of audio-only services to patients and the healthcare system has proven significant, and this progress should not be lost.** While the medical community may be currently adjusting and learning how to most effectively schedule, conduct and implement audio-only visits, the ACC believes it is an effective tool to ensure patient access to care now and in the future. The ACC strongly recommends creating a durable financial mechanism to appropriately support this type of patient visits.

Finally, CMS should allow conditions addressed during a telephone only visit to count for the purposes of Medicare Advantage hierarchical condition category (HCC) coding. These interactions are meaningful for patient care and will more thoroughly inform risk-adjustment model estimates if included.

Technical Update

CMS proposes to remove the second sentence of the regulation at § 410.78(a)(3) which specifies that “[t]elephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.” CMS expresses concern that the reference to “telephones” in the second sentence of the regulation as impermissible technology could cause confusion in instances where an otherwise eligible device, such as a smart phone, may also be used as a telephone. **The ACC**

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appreciates CMS' concern and supports the removal of this sentence from the regulation. Advances in digital communication technology such as smartphones (noted by CMS), tablets, smart devices, VoIPs (Voice Over Internet Protocols) should not be unnecessarily excluded as communication methods for patients and clinicians to utilize for telehealth services.

Valuation of Specific Services

Codes for many cardiovascular and related services were reviewed by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) during the CY 2020 cycle. Detailed comments on changes CMS proposed to the RUC recommendations for many of these services follow below. The ACC coordinates with stakeholder societies, so some pieces of feedback on specific code values may echo others' comment. The Agency also proposed to implement several sets of recommendations without modification. The ACC supports work proposals related to, percutaneous ventricular assist device insertion, complete electrocardiogram, external extended ECG monitoring, complete transthoracic echocardiography (TTE) with doppler, and exercise test for bronchospasm, and the PE proposals for myocardial PET equipment, complete electrocardiogram, complete transthoracic echocardiography (TTE) with doppler.

Atrial Septostomy (CPT codes 33XX0, 33XX1, 33XX2)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
33XX2	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catheterization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)	8.00	10.50

Societies worked to update the codes for atrial septostomy to incorporate image guidance and expand their application to more complex procedures not previously performed when the original septostomy codes were created. The ACC appreciates that CMS proposes to adopt recommendations from the RUC

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for two of the three codes in the family. For the third code, 33XX2 (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catheterization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)*), CMS proposes to use the survey 25th-percentile work RVU of 8.00 instead of the 10.50 median work RVU recommended by the RUC, noting both the difference in time between 33XX2 for an additional stent and 33XX1 for the initial stent placement as well as comparing it to key reference code 93592 (*Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)*) that has an identical intraservice time.

Basing valuation on the value on the identical time of 93592 is flawed because it ignores the recognized significantly increased intensity and complexity of placing a stent within the beating heart with the risk of the stent embolizing from the intended location. Although 93592 also involves placement of a device or coil within the beating heart, all devices and coils used for repairing a paravalvular leak are easily retrieved, removed, and/or repositioned should they move from their intended location. Once a stent is delivered, if not perfectly positioned, the only recourse is emergent open-heart surgery, in a patient for whom surgery was already deemed too high a risk, even in ideal, elective circumstances. Add to this the typical patient having procedure 33XX2 is a small child or infant, and the complexity rises significantly as compared to the adult patient for 93592. Finally, other CPT codes for each additional stent scenarios, are purely intravascular and the repositioning for delivery of the additional stent is minimal work. For intracardiac purposes, 33XX2 is not intended as an extension of an initial stent. That is covered entirely by 33XX1. Rather, the lesions covered by the work for 33XX2 are entirely distinct from that covered by 33XX1 and require considerable work to reposition all necessary catheters and wires for the additional stent procedure. The RUC correctly recognized this difference and recommended the survey median because of these vital differences. At the 10.50 value, the add-on 33XX2 has a calculated intraservice intensity that is higher than the key reference service but lower than 33XX1 for the placement of the initial stent. **The ACC urges CMS to reconsider and finalize the survey median work RVU of 10.50 the RUC recommended.**

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Pacing Heart Stimulation (CPT Code 93623)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
93623	Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)	0.98	2.04

For the Pacing Heart Stimulation code (93623), CMS has disagreed with the RUC recommended work RVU. CMS has proposed to decrease the work RVU from 2.04 to 0.98 for code 93623. CMS believes that their pick of an alternate work RVU more closely aligns with the valuation of this code than the RUC recommended. However, the RUC recommended work RVU for code 93623 is based on survey data. CMS should use valid survey data in establishing the work RVU for this code. The RUC thoroughly analyzed this code by review of history, survey data and magnitude estimation to other similar services. Details on why CMS should accept the RUC recommendation for this code are outlined below. The RUC recommended a work RVU of 2.04. CMS disagrees with the RUC recommended work RVU of 2.04 and is proposing a work RVU of 0.98 for code 93623 based on the significant change “from the current 60 minutes to 20 minutes” in intra-service/total time. The Agency does not believe that the RUC recommended work RVU appropriately accounts for the reduction in intra-service time for this service. The College completely disagrees with CMS’ proposed recommendation of 0.98 work RVUs for code 93623. The current time source for CPT code 93623 is CMS-Other. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work. This code’s source of time is CMS-Other, implying that the time was merely crosswalked or selected by a single CMS analyst decades ago.** CPT code 93623 has never been surveyed by the RUC; the intra-service time established by the CMS-Other source is what the current work RVU is based on. Therefore, CMS’ rationale to further reduce the recommended work RVU based on the reduction of the “current” intra-service time of 60 minutes in comparison to the RUC recommended intra-service time of 20 minutes from robust survey data for code 93623 is unjustified. Additionally, the RUC’s recommendation of 2.04 for code 93623 will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

Furthermore, CMS compares code 93623 to reference code 76810 (*Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)*) (work RVU = 0.98, intra-service and total time of 20 minutes). CMS is incorrect in proposing the work RVU of 0.98 when referencing code 76810 because the nature of the services

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performed, time, intensity and work involved are vastly different. The only commonalities between 93623 and 76810 are that they are both add-on codes and have 20-minute intraservice times. 76810 includes supervision of sonographer and interpretation of an ultrasound of an additional fetus—e.g., a twin. During 93623, isoproterenol is infused to the heart through a central line port, ideally increasing the patient's heart rate 20% above baseline, during a 60-minute period. Isoproterenol is a potent nonselective beta-adrenergic agonist with very low affinity for alpha-adrenergic receptors. Intravenous infusion of isoproterenol lowers peripheral vascular resistance thereby decreasing diastolic pressure. Cardiac output is increased because of the positive inotropic and chronotropic effects of the drug in the face of diminished peripheral vascular resistance. The cardiac effects of isoproterenol may lead to palpitations, sinus tachycardia, and more serious arrhythmias, which may ultimately require treatment via catheter ablation. A patient requiring isoproterenol experiences transient episodes of heart block, while a patient receiving the ultrasound is simply found to have twins, a vastly different state of health; one requiring observation and the other requiring treatment. Pacing stimulation is significantly more intense with acute risk to the patient during an already complex, underlying procedure.

The RUC recommendation for CPT code 93623 was based on the survey 25th percentile work RVU from robust survey results of 46 cardiologists as well as a favorable comparison to the top key reference service (KRS) 93463 *Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (List separately in addition to code for primary procedure)* (work RVU = 2.00 and intra-service time of 30 minutes). Survey respondents who selected the pharmacologic agent administration code 93463 as the top key reference service found code 93623 to be more intense/complex overall. The RUC agreed that this comparison is reasonable since survey respondents estimated CPT code 93623 to involve a similar amount of work to CPT code 93463. The RUC also referenced MPC code 36227 *Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)* (work RVU = 2.09 and intra-service time of 15 minutes) and agreed that both reference services bracket code 93623 in both physician work and time, strongly supporting the RUC recommended work RVU of 2.04. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS-Other, implying that the time was merely crosswalked or selected by a single CMS analyst decades ago. The ACC requests CMS independently review the surveyed time and work and not compare it to the invalidated CMS-Other source of the current time and work. The ACC strongly urges CMS to accept a work RVU of 2.04 for CPT code 93623.**

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Intracardiac Echocardiography (ECG) (CPT code 93662)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)	1.44	2.53

For the Intracardiac Echocardiography code (93662), CMS has disagreed with the RUC recommended work RVU. CMS has proposed to decrease the work RVU from 2.53 to 1.44 for code 93662. CMS believes that their pick of an alternate work RVU more closely aligns with the valuation of this code than the RUC recommended. However, the RUC recommended work RVU for code 93662 is based on survey data. CMS should use valid survey data in establishing the work RVU for this code. The RUC thoroughly analyzed this code by review of history, survey data and magnitude estimation to other similar services. Details on why CMS should accept the RUC recommendation for this code are outlined below.

The RUC recommended the survey 25th percentile work RVU of 2.53 for CPT Code 93662. CMS disagrees with the RUC recommended work RVU of 2.53 and is proposing a work RVU of 1.44 for code 93662 based on the Agency's assumption that "significant decreases in time should be appropriately reflected in decreases to work RVUs." The College completely disagrees with CMS' proposed recommendation of 1.44 work RVUs for code 93662. The RUC recommended work RVU and time for code 93662 reflects the change in technology from when it was last valued in 2000. Intracardiac echocardiography has become an essential tool for complex catheter ablation of many types of arrhythmias and it has also enabled operators to significantly reduce the use of fluoroscopy. Since this service was last valued in 2000, arrhythmia mapping systems have developed the ability to incorporate intracardiac echo images into 3-dimensional electro-anatomical maps. This has improved the accuracy, safety and effectiveness of catheter ablation for a wide range of arrhythmias, most notably atrial fibrillation. Additionally, the RUC's work RVU recommendation for code 93662 will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

CMS references code 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)*) (work RVU = 1.44 and 25 minutes of intra-service time) as a "good equivalent comparator code in light of the significant physician time

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reduction from 55 minutes" to 25 minutes in intra-service time for code 93662. CMS is incorrect in proposing the work RVU of 1.44 when referencing code 92979 because the nature of the services performed, intensity and work involved are different, with the two services performed in different parts of the heart for different reasons. Coronary IVUS is performed inside the coronary arteries to guide diagnostic catheterization and/or percutaneous coronary interventions.

ICE is used to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of a catheter location within the heart. It commonly guides trans-septal puncture—where the operator creates a hole in the septum of the heart to gain access to the other cardiac chambers on the other side of the heart—and is useful for early recognition of procedural complications, such as pericardial effusion or thrombus formation. ICE is remains highly technical in nature and requires the patient to be anesthetized, which is not required in IVUS use. It is most commonly used with atrial fibrillation ablations, a highly technical and challenging service in its own right, the reinforces the intensity of ICE. The interpretation of IVUS images is less complex than interpretation of ICE images, similar to the difference between looking at the cross section of a garden hose versus a cross section of an apartment building.

The RUC recommendation for CPT code 93662 was based on the survey 25th percentile work RVU from robust survey results of 42 cardiologists as well as a favorable comparison to code 34713 *Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral (List separately in addition to code for primary procedure)* (work RVU = 2.50 and intra-service time of 20 minutes) and MPC code 36476 *Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)* (work RVU = 2.65 and intra-service time of 30 minutes). Both reference services bracket code 93662 in both physician work and time. **The College strongly urges CMS to accept a work RVU of 2.53 for CPT code 93662.**

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Ventricular Assist Device (VAD) Interrogation (CPT code 93750)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report	0.75	0.85

Utilization of code 93750 (*Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report*) has appropriately grown as more VADs have been used and need to be interrogated. This growth spurred review of the RUC, and the ACC worked with other societies to complete a physician work survey. That survey generated results that would have led to an increased work RVU valuation, which was not deemed acceptable given the reduction in service time. The societies did note significant changes in the service from its initial valuation, including a change from surgeons using it to confirm proper function to heart failure cardiologists using it to calibrate care and a failure of the existing inputs to delineate between service period increments, making it impossible to know whether changes in time were driven by meaningful changes in effort or modest changes in documentation through the use of EHRs.

Nevertheless, societies and the RUC agreed that a modest reduction by crosswalk to a service with similar service times was appropriate, selecting 78598 (*Quantitative differential pulmonary perfusion and ventilation (eg, aerosol or gas), including imaging when performed*). CMS goes through the same exercise but proposes a different code with similar times that has an even lower value, 93289 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements*). This is a service the societies considered as a crosswalk but abandoned because it does not involve device programming, which the VAD service does, as the device speed is frequently adjusted to optimize performance. Instead, that realization prompted search for

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the crosswalk ultimately recommended by the RUC that is appropriately slightly higher than the defibrillator interrogation service.

Finally, while both the ICD and VAD patients are ill, the VAD patients have heart failure that has deteriorated to such a degree that a pump has been inserted into their chest to support their heart while they await a transplant or to improve the quality of their remaining life. The underlying illness is different, and the RUC-recommended, slightly higher crosswalk appropriately recognizes that difference. **As such, the ACC recommends CMS revise the work RVU for 93750 in the final rule and implement the RUC recommendation of 0.85 that incorporates an increment above the crosswalk value proposed by CMS.**

Practice Expense (PE) Refinements

Throughout rate setting for specific codes/services, CMS made several changes from RUC recommendations to practice expense inputs of interest to ACC. These are summarized in Table 25 of the proposed rule. The ACC provides detailed responses to some of those refinements here, and has also shared this perspective with other stakeholders and the RUC.

For *Extended External ECG Monitoring* codes, the ACC agrees that one pair of non-sterile gloves should be removed, correcting a summing error in the practice expense spreadsheet. However, the ACC disagrees with the removal of five minutes of clinical staff time from four of the codes in the family. CMS proposes that 5 minutes in CA021 be removed as some of the clinical staff work description, "incoming patch deliveries are sorted and distributed to work queues. The return box is opened, diary book removed, top housing is removed using a custom tool to expose USB connection, and device is plugged in to extract serial number and diagnostic logs" is deemed an administrative cost and, therefore, indirect. Delivery and assignment may be fair to characterize as administrative, but accessing the device, connecting it, and downloading data seems more akin to CA032 when clinical data is put into the system. **The ACC recommends CMS reduce clinical staff time by one minute, not five, to account for the delivery sorting, distribution, and box opening.**

In discussing inputs for *Complete Transthoracic Echocardiography with Doppler*, CMS indicates recommendation materials indicated both 25 mL and 50 mL of ultrasound gel for the service. The 50 mL amount was an editing error. The 25 mL amount is the correct one, which aligns with the proposed input.

Finally, direct inputs for External Counterpulsation have proven challenging to reflect correctly for the past three rulemaking cycles. Some External Counterpulsation refinements in this proposed rule are fairly straightforward while others are more challenging.

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CMS proposes to move three minutes for vitals at the end of the session to post-procedure monitoring. **The ACC disagrees with this change, as this is not monitoring in the sense of CA023 but taking vitals to evaluate the effectiveness of the treatment and the patient's condition.**

The ACC has previously recommended creation of new equipment packages that capture previously unrecognized costs. CMS instead proposes to create new inputs as supplies rather than equipment. This approach could be effective if the pricing and consumptions are accurate. CMS proposes to reduce the cost of new supply input SD342 for electrical equipment and disperse it over 325 sessions. The inputs recommended by the ACC and the RUC were for an equipment package of \$565 and a one-year lifespan. As a supply, that should still be \$565, rather than the \$500 proposed. Over the course of a year that would be expected to be 400 sessions, so the consumption rate would be 1/400th per session.

Proposals regarding new supply input SD341 for a compression supply package parallel electrical package SD342. CMS proposes the RUC-recommended price of \$650 for this item and disperses it over 325 visits. The ACC has identified two flaws with this proposal. First is that the RUC recommended inclusion of items in the compression package believed to be most predictably and consistently replaced at regular intervals—compression cuffs, hoses, and bladders. These are replaced every 100 hours of service, so the consumption rate should be 1/100th of the supply package, not 1/325th. The second flaw is that the price of the supply package for necessary cuffs, hoses, and bladders was summed incorrectly. Information originally submitted to the RUC by ACC in 2019 included thigh cuff at \$170, calf cuff at \$75, bladders at \$65, and hoses at \$390. That should make the package \$700 based on understanding of the information assembled last year. It is not clear to ACC whether that error was made at the RUC meeting at some later time.

As CMS and the RUC know from consideration of this topic the past three cycles, this service is not provided by many practices, something that came to light when attempting to survey the code for physician work in 2017. It has proven challenging for the ACC to collect information because of the limited number of providers. Stakeholders who provide the technical component of external counterpulsation at significant volumes are better positioned to provide further insights to the service and whether proposed inputs and these suggested refinements correctly reflect the direct costs. Additional information from other stakeholders may further improve the accuracy of these inputs.

Prothrombin/International Normalized Ratio (PT/INR) Indirect PE Crosswalk

Responding to stakeholder input, CMS solicits feedback from the public regarding potential specialty crosswalks to account for costs that are different for PT/INR home monitoring than other independent diagnostic testing facility services. ACC is not equipped to say which specific indirect factors may be optimal for crosswalk due to a lack of information on direct:indirect cost data from the suppliers.

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However, the College does wish to highlight the importance of ensuring sure that home INR monitoring rates are adequate to assure access. One large provider recently sold their home anticoagulation monitoring business and it is not clear that the service will remain viable in long term if some reversal of the significant reductions in recent years is not made.

Remote Physiologic Monitoring (RPM)

CMS proposes several clarifications to address interpretation questions regarding RPM services. These include, (1) the medical device(s) supplied to the patient and used to collect physiologic data are considered equipment and as such are direct PE inputs, (2) provision of multiple medical devices to a patient does not mean an RPM code can be billed multiple times, (3) the utilized medical device should digitally (automatically) upload patient physiologic data, (4) as E/M codes, these services can be ordered and billed only by physicians or nonphysician practitioners (NPPs) who are eligible to bill Medicare for E/M services, (5) RPM services may be furnished to analyze physiologic data from patients not only with chronic conditions as previously suggested, but also with acute conditions, (6) like other care management services, RPM can be furnished by clinical staff under the general supervision of the physician or NPP, (7) “interactive communication” means “real-time synchronous, two-way interaction that is capable of being enhanced with video or other kinds of data transmission” between the patient and physician, NPP, or clinical staff. The ACC believes these clarifications will aide in proper provision of the service and ease documentation uncertainties.

Reflecting lessons learned during the PHE, CMS also proposes to make permanent two policy changes from interim final rulemaking earlier this year. First, CMS proposes to permanently allow consent to be obtained at the time RPM services are furnished. Second, that this consent acquisition task can be completed by auxiliary personnel who need not be clinical staff. **The ACC supports these proposals to ease access to RPM in this manner.**

Scope of Practice and Related Issues

In the past, services provided by physicians in training and resident physicians, had numerous restrictions limiting them from being directly billed to Medicare. Services furnished by these physicians-in-training could be billed as a service of a supervising teaching physician, given that the teaching physician was physically present for key parts of the encounter. The Agency’s proposal, however, would allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests, in addition to physicians. Prior to the May 1st COVID-19 IFC, these nonphysician practitioners were already authorized under Medicare regulations to order and furnish diagnostic tests, while as a basic rule, generally only physicians (medical doctors and doctors of osteopathy) were authorized to supervise the performance of diagnostic tests. However, if finalized on a permanent basis effective

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January 1, 2021, NPs, CNSs, PAs and CNMs would be allowed under the Medicare Part B program to supervise the performance of diagnostic tests within their state scope of practice and applicable state law, provided they maintain the required statutory relationships with supervising or collaborating physicians.

The College believes a distinction exists between the ability of advanced practice providers (APPs) to perform tasks autonomously and their ability to practice independently. The former is a well-established practice, while the latter is controversial for some. **The College focuses on the value of cardiovascular APPs practicing autonomously as part of the cardiovascular care team but not as independent practitioners.** Similar to the changes already achieved by the Improving Access to Cardiac and Pulmonary Rehabilitation Act of 2018, a number of cardiovascular diagnostic tests that require direct supervision are candidates to be provided under a physician's general supervision when clinical staff are also under the direct supervision of appropriate APPs. These instances would parallel supervision level 4 where a clinical psychologist may personally furnish or generally supervise services. **The ACC believes CMS should change supervision levels for these tests, similar to those it has under supervision level 4, allowing APPs under general supervision of a physician to personally furnish or directly supervise other clinical staff.**

The technical components of cardiovascular stress tests, cardiac device interrogation, and anticoagulation management are all services for which an APP under the general supervision of a physician can reasonably provide direct supervision of other APPs, nurses, or technicians. While many practices would continue to utilize direct physician supervision for these services, others that have highly trained APPs could become more efficient by relying on proficient APPs who have demonstrated necessary core competencies.^{1,2} Such a change would allow flexibility in instances where the practice environment is spread across a geographic area (multiple buildings, clinics or hospitals for a single practice or a rural access facility staffed remotely). Such a requirement can be unnecessary in instances where there are experienced, clinically competent APPs who can provide these services under general physician supervision to expand access to care and enable cardiologists to focus on services only they can offer. The College strongly believes all members of the cardiovascular care team should exhibit the necessary core competencies in their practice of medicine to ensure patient safety and minimize exposing the patient to risk.

¹ Coats and Oaks (2018). Supervision of Stress Testing by Nonphysicians. Thomas, Wann, and Ellestad. *Ellestad's Stress Testing*, (Chap 12).

² This chapter reviews the opportunity and competency requirements of advanced practice nurses supervising exercise and vasodilator stress tests. Step-by-step recommendations for test performance by nonphysicians is reviewed including preparation, review of patient history and past diagnostic testing, test supervision, and reporting. Guidelines for exercise physiologist supervision of exercise testing are discussed.

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Direct Supervision by Interactive Telecommunication Technology

Consistent with the May 1st COVID-19 IFC (85 FR 27562), CMS proposes revising the definition of direct supervision to permit virtual presence of the supervising clinician. CMS proposes to clarify that services that may be billed incident-to may be provided via telehealth incident to a physicians' service and under the direct supervision of the billing professional. More specifically, the proposed rule explains that direct supervision in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of [this proposed rule] or, December 31, 2021, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only). The College is cautiously supportive of these proposed changes. **In certain circumstances, when the technician, nurse, or other health care provider, on staff is appropriately trained, the College believes direct supervision to permit virtual presence enhances the ability of the cardiovascular care team to provide appropriate care to their patients.** For example, the interrogation of cardiac implantable electronic devices (CIEDs) including pacemakers, implantable cardioverter defibrillators (ICDs), and loop recorders, has increased over the past several years.³ While patients are supported by remote home monitoring, they often need device interrogations in the clinic setting to assess device settings, evaluate stored events, or determine the cause of syncope or defibrillator discharge. In this case, pacemaker/ICD technicians or pacemaker nurses, or other clinical personnel are highly trained and capable of performing the in-office interrogation. At times, the supervising physician is on hospital grounds, not directly present with the clinician, but in a separate hospital building overseeing the procedure virtually. The College believes this clinical scenario is a good example where virtual supervision is both appropriate for the patient and also an efficient use of hospital resources. **The College encourages CMS to allow this virtual presence of the supervising physician, as long as other members of the cardiovascular care team are appropriately trained and licensed.**

Removal of Selected National Coverage Determinations

In a process shift, CMS proposes to use the fee schedule rulemaking process to remove outdated NCDs rather than the NCD process. The ACC does not believe one mechanism or the other is superior, though the fee schedule rulemaking process may shine a brighter light on such proposals and encourage wider feedback. The ACC is familiar with one of the NCDs proposed for removal, 220.6.16 FDG PET for Inflammation and Infection, and agrees with CMS that removal of the NCD would allow for more appropriate coverage decisions than the current NCD. Diagnosis/assessment of cardiac sarcoid is

³ Mond G, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009—a World Society of Arrhythmia's project. *Pacing Clin Electrophysiol*. 2011;34(8):1013-1027.

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one area for which positive coverage is supported by the latest literature. **The ACC supports removal of NCD 220.6.16.**

With regard to the length of time used in these reviews, 10 years may be too long to keep pace with current science and clinical developments. Some hybrid of annual review as an opportunity to remove obviously outdated NCDs with 10 years as a marker for an additional level of scrutiny may be effective to maintain NCD relevance. This would require an additional level of effort and commitment that may prove challenging for CMS and stakeholders to manage.

CY 2021 Updates to the Quality Payment Program (QPP)

The ACC appreciates the opportunity to provide comments on Year 5 of the QPP. Participation in both tracks of the QPP –Advanced Alternative Payment Models (APMs) and Merit-based Incentive Payment System (MIPS)—has increased. In addition, 98 percent of eligible clinicians participating in MIPS received a positive payment adjustment for 2020 based CMS-1734-P 592 on 2018 performance year results. The College thanks CMS for the extension of the 2019 data submission period due to the COVID-19 PHE and the ability to apply for reweighting of performance year 2020 categories based on the COVID-19 PHE. The ACC encourages the Agency provide the 2019 MIPS participation data as soon as possible, so that physicians can more quickly implement further refinements to the program.

In reviewing the comments provided in the following sections, the College requests that CMS:

- Continue efforts to prevent the QPP from being an administrative burden on clinicians;
- Finalize programs that adequately balance flexibility with quality patient care;
- Provide clinicians with meaningful measures appropriate to the patient population of interest;
- Provide enough time for the development of novel paths and frameworks to meet QPP performance goals in the following year and years to come;
- Continue to eliminate barriers to APM participation.

MIPS Program Updates

CMS proposes to continue to incrementally adjust the performance threshold and performance category weights to meet the requirements established by the statute. Beginning with the sixth year of the program (2022 performance period), the performance threshold needs to be set at the mean or median of the final scores for all MIPS eligible clinicians for a prior period, and the Quality and Cost performance categories must be equally weighted at 30% each.

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Quality Performance Category

CMS proposes the reduction of the Quality Performance Category to 40 percent in 2020, 35 percent in 2021, and 30 percent in 2022. For performance year 2022, CMS proposes to remove 55 measures due to minimal adoption, duplication, and “topped out” status. The proposal also looks to add seven new specialty sets that address the eligible clinician groups that were added in CY 2019 final rule, changes 78 measures and adds four new measures addressing functional status, immunization status and pain management.

The ACC asks the Agency to ensure that clinicians are aware that a measure with substantive changes may lose its historical benchmark. The loss of historical benchmark translates to measures potentially only earning a maximum of 3 points, even though the prior-year iteration of that measure could earn up to 10 points. The College believes ensuring transparency with participating and eligible clinicians will continue to facilitate program participation.

As stated in previous comment letters, the College continues to oppose the removal of topped out measures from the QPP and asks CMS to exercise caution when eliminating measures. While there is good intention in reducing administrative burden by reducing the number of quality measures a physician must report under the Quality category, the removal could be completed in a phased approach. A phased or delayed approach would provide more time to measure stewards to provide input on the value of measures, and also provide clinicians with time to determine whether or not to continue reporting the measures. Drastic reduction goes against the goal to implement more outcome measures and also reduces the level of flexibility that clinicians are offered by limiting their selection to less clinically relevant measures to report. **The ACC encourages CMS to work with measure stewards to determine if removal is appropriate.**

Measure Update: Hospital-Wide 30-day, All-Cause Unplanned Readmission (HWR) Rate

In this proposal, CMS is replacing the All-cause Hospital Readmission measure with a Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups because the re-specified measure promotes a system level approach by clinicians, with a focus on high risk conditions such as chronic obstructive pulmonary disease (COPD) and heart failure. This measure has been reviewed by the National Quality Forum (NQF) and recommended for endorsement at the group level only and with a minimum of 200 cases. While the College appreciate the measure developer’s efforts to provide additional justification for attribution to the three types of clinician groups, the ACC believes that the evidence falls short of demonstrating clear attribution to decreased readmission rates. In addition, the ACC believes the reliability levels for the cardiorespiratory and cardiovascular cohorts continue to be too low for acceptable use. Furthermore, the College has additional concerns as it relates to heart failure patients. Prior attempts to reduce readmission rates for this patient

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population was associated with a reduction in the rate of readmissions, but also an increase in the rate of death among Medicare patients hospitalized with heart failure.⁴ In light of these concerns, **the ACC encourages CMS to ensure these issues are considered as the measure continues through development and the endorsement process at NQF.**

Cost Performance Category

CMS proposes to increase the weight of the Cost performance category to 20 percent in 2021, and 30 percent in 2022 and all subsequent MIPS payment years. The goal of these changes is to align Quality and Cost performance categories to create better value and to gradually work toward equal weighting, which is required by statute.

As the Cost category continues to increase under MIPS, CMS must ensure that clinicians are fairly measured. **The ACC continues to have concerns with use of the claims-based Total Per Capita Cost (TPCC) and Medicare Spend Per Beneficiary (MSPB) measures, as they may hold clinicians attributable for services outside of their control.** While the College appreciates efforts to revise these measures, additional work is needed to improve attribution methodologies used not only in the MIPS Cost category, but across all CMS programs.

Total Per Capita Cost Measure & Medicare Spending Per Beneficiary Clinician Measure

The ACC recognizes the importance of cost assessment in pay-for-performance programs such as through the Medicare Spending per Beneficiary (MSPB, NQF #3574) Clinician and Total Per Capita Cost (TPCC, NQF #3575) measures. The ACC has been monitoring the NQF endorsement process of these measures via the Cost & Efficiency Standing Committee, being mindful of the methodology to ensure that the true costs of episode-based care are assessed accurately for specialist clinicians who may only serve a small part in the care delivery process.

Some concerns were raised for both measures during the Committee's recent July 2020 committee deliberations. We recommend that CMS address these issues with the measure developer before further implementation. In particular, the Committee raised the following concerns about the MSPB measure: attribution to multiple clinicians and whether a care episode could be attributed to multiple clinician groups and multiple clinicians, the validity of the time window of three and 30 days pre- and post-discharge for each episode, the ability of the model to predict downstream costs after a hospitalization, and lack of inclusion of social risk factors. It is also unclear if beneficiaries will find this type of information useful or meaningful in distinguishing clinician performance. Since the committee's final vote was "not recommended for endorsement," **the College find this concerning and encourages**

⁴ Gupta A, Allen LA, Bhatt DL, et al. Association of the Hospital Readmissions Reduction Program Implementation With Readmission and Mortality Outcomes in Heart Failure. *JAMA Cardiol.* 2018;3(1):44–53. doi:10.1001/jamacardio.2017.4265 /

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CMS and the measure developer to address these issues related to validity if the measure will continue to be used in federal programs.

NQF's Cost & Efficiency Committee also continued to express validity concerns over the TPCC Measure. The correlation with risk- and specialty-adjusted costs were considered low to moderate, and there continues to be a lack of social factors in the risk-adjustment model. While the developer reported that inclusion of social factors in the model did not significantly change TIN or TIN-NPI performance scores on average, **CMS should still consider revising the risk-adjustment model to include social factors that are likely to influence the clinical health status of the population under consideration.**

The College appreciates the measure developer's continued refinement of the complex attribution methodology and the intent to improve care coordination among providers. The concern remains that a larger than ideal number of clinicians may erroneously be attributed costs over which they have no control. In addition, the CMS definition for adequate or moderate reliability using the 0.4 threshold is typically considered low and is likely not suitable as it pertains the measure score testing results. Particularly for specialist clinicians, this measure may be suboptimal for helping to drive meaningful improvements in care efficiency, as multiple clinicians can be attributed to the measure unrelated to practicing team-based care. As these inherent limitations to the measure caused the Cost & Efficiency Committee to delay a vote due to a lack of consensus, the College perceives that the measure is not in fact measuring what it is intending to measure.

Improvement Activity Performance Category

In section IV.A.3.c.(3)(b)(i)(A)(aa) of this rule, CMS is proposing to make an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Additionally, CMS is proposing, beginning with the CY 2021 performance period and future years, to consider agency-nominated improvement activities. **The College thanks CMS for the flexibility in allowing stakeholders to nominate improvement activities outside the established Annual Call for Activities timeframe.**

Promoting Interoperability Performance Category

CMS and ONC have continued to focus on methods for reducing administrative burdens directly related to reporting Promoting Interoperability and other programs. The finalized CMS and ONC Interoperability, Information Blocking, and Patient Access rules put forth a framework that would advance Certified Electronic Health Record Technology (CEHRT) requirements towards the realization of true interoperability. The ACC thanks CMS and ONC for their efforts to reduce administrative

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burdens and improve interoperability encourages continued work to align reporting requirements across care settings, eliminating redundancies and streamlining objectives and measures.

CMS proposes retaining a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. **The ACC thanks CMS for continuing the 90-day reporting period and encourages CMS to further align the promoting interoperability programs for the Medicare and Medicaid programs through common measures and reporting periods.** By providing continued program stability, CMS allows EPs to focus on caring for patients and improving interoperability rather than prescriptive reporting requirements.

CMS also proposes adding a new, optional measure under the Health Information Exchange (HIE) objective beginning with the performance period in 2021: Health Information Exchange (HIE) Bi-Directional Exchange. Clinicians either may report the two existing measures (Support Electronic Referral Loops by Sending Health Information and Supporting Electronic Referral Loops by Receiving and Reconciling Health Information) and associated exclusions or may choose to report the new optional alternative measure. **The ACC supports CMS' proposed creation of an optional measure that encourages development of bi-directional information exchange.** The ACC has long called on CMS to focus the PI program on a limited handful of high value initiatives that aim to promote true interoperability, increase the usability of EHR systems, promote clinical data standards, and reduce the amount of necessary manual tasks such as patient matching or data abstraction. The College also appreciates that attestation requires information exchange for all patients and for all patient records without exclusion, exception, or allowances made for partial credit. By including this language, CMS works to ensure all patients will benefit from bi-directional exchange rather than allowing for the cherry picking of specific, easy electronic transfers of information.

Qualified Clinical Data Registries

Beginning in the 2022 performance period, CMS is requiring QCDRs to license their measures to other QCDRs and have measure testing completed at the time they submit their application to CMS. While CMS has opted to roll out a two-step process that first requires face validity testing and eventually full measure (beta) testing, **the College is still concerned about this requirement, as the testing process can be significantly arduous and funding, staff, and other resources have been significantly reduced due to the COVID-19 PHE.** As stated in previous comment letters, the College estimates it may take at least a year to develop a measure, which requires considerable input and work from both physicians and society staff. At this time, focus is being given to patients, policy, and payments directly impacted by COVID-19 PHE. As such, the time and staff resources that it would take to devote to measure development and testing, are unavailable to most stakeholders. Testing can also be very expensive. Given the number of budget cuts that hospitals, offices, and other stakeholders across medicine are

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undergoing during the PHE, the financial resources available to devote to this effort are also unavailable and it is unknown when ‘normal’ resources would be available once again. **While the College appreciates the delay in implementation, the College asks CMS to push this full testing timeline back to 2023 or later.** Failing to take these concerns into consideration may result in interested parties opting to not participate in the QCDR program. Similarly, CMS also proposes the QCDR measure data collection requirement be delayed until at least the 2022 performance period in light of the pandemic. QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. **For the reasons stated above, the College asks CMS to push this timeline back at least one year.**

Advanced Alternative Payment Models (Advanced APMs)

The ACC supports the proposal to not revoke Advanced APM status for any entity that met the threshold during CY 2020 but had to end participation due to the COVID-19 PHE. The pandemic has placed a strain on many entities as clinical and financial resources were redirected to treat those with the virus and prevent the infection of others. This proposal would continue to provide an incentive to those who participated in an Advanced APM in 2020 but saw lower patient volume during the pandemic or had to withdraw due to the inability to continue assuming downside risk.

In addition, the ACC supports the proposal to implement a targeted review process for Advanced APM participants. The targeted review process allows clinicians to submit a request for review if they believe CMS has erred in their Advanced APM qualified provider status determination. The targeted review process already exists under MIPS; the ACC supports the extension of this process to Advanced APM determinations.

Medicare Shared Savings Program (MSSP)

The ACC applauds CMS 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 broad impact of COVID-19 on care delivery, the ACC requests that CMS consider flexibility for all participants regardless of the number of COVID-19 cases treated.

The uncertainty of defining a timeline for the COVID-19 crisis continues to be a concern for the ACC for several reasons. 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 extreme and uncontrollable circumstances policy uniformly to all participants nationwide until the end of the performance year would prevent the need for CMS to later modify the program on a regional basis. In addition, while the College greatly hopes that the country does not experience a

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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.

The College is concerned that the clinical and financial impact of the pandemic, combined with future uncertainty, may cause many participants to either drop out of voluntary models or feel forced to assume downside risk for an unanticipated and unprecedented population. The ACC recommends that CMS continue to assess the need for modifications to support continued participation in these programs and maintain the move to value.

Beneficiary Attribution

The ACC acknowledges CMS' interest in considering all accountable care organizations (ACOs) affected by the Public Health Emergency (PHE) for the COVID19 pandemic and applying the Shared Savings Program extreme and uncontrollable circumstances policy for performance year 2020. The ACC also acknowledges CMS' proposal to "determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries, rather than the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which is currently used."

However, the College believes that it is difficult to calculate who exactly is affected by COVID-19 and that the beneficiary attribution definition should cover a wider range of patients. At the beginning of the pandemic, the key areas that were harder hit and the hospitals that were inundated with COVID-19 make it more difficult to determine what percentage of the population was affected. In these circumstances, almost 100 percent of the patient population was affected by the pandemic, whether due to the virus itself, practices put in place to ensure social distancing, or patient fear of seeking care. Additionally, during the months of March and April 2020, many of these hospitals did not have access to widespread testing so there were a higher number of presumed COVID cases. Many patients at this time also were tested and never displayed symptoms. Even now, COVID testing remains problematic so it is difficult to get a true sense of how many patients are truly affected by the pandemic because many states continue to not have as much access to testing as others. **The College would like to see this policy cover a broader beneficiary population and not be limited only to those patients documented with a COVID-19 diagnosis.**

Adjusting Shared Savings Amount for Affected Participants

CMS also proposes a potential alternative extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years that would continue to incentivize reporting but would also acknowledge the challenges presented by extreme and uncontrollable circumstances. This

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proposal would create a “methodology that would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting.”

Under this alternative approach, instead of determining that ACOs are affected by an extreme and uncontrollable circumstances, CMS proposes that “if 20 percent of their beneficiaries or their legal entity are located in an area impacted by an extreme and uncontrollable circumstance and determining shared savings using the higher of the ACO’s own quality score and the mean ACO quality score, CMS would determine shared savings for an affected ACO by multiplying the maximum possible shared savings the ACO would be eligible to receive based on its financial performance and track (or payment model within a track) by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO’s assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.”

The College supports the proposal to continue the extreme and uncontrollable circumstances policy for PY 2022 and subsequent years in order to keep participants in program who have been impacted by both natural disasters and/or the COVID-19 pandemic. This opportunity would allow participants to have flexibility on reporting and be able to use prior scoring due to the pandemic affecting scores given the unknown impact.

Quality Performance Threshold

CMS proposes to increase the level of quality performance required by ACOs to meet the MSSP quality performance standard for performance year 2021. CMS proposes to require “a quality performance score equivalent to the 40th percentile or above across all MIPS quality performance category scores excluding entities/providers eligible for facility-based scoring.” CMS estimates that 95% of participants meet or exceed this threshold.

While this proposal seems reasonable to consider, the College does not believe that now is the right time to implement raising the performance threshold in light of the COVID-19 pandemic and the natural disasters such as the hurricanes and wildfires that have impacted parts of the country. The estimation of 95% of participants being able to meet or exceed the performance threshold is based on historical data where there were no extreme or uncontrollable circumstances as far-reaching as the pandemic to take into consideration. Participants are experiencing new levels of uncertainty as they do not know how the pandemic will impact their performance on the MSSP quality metrics. **Therefore, the ACC recommends that CMS delay this proposal and not implement it until 2022 at the earliest. If CMS finalizes this proposal for 2021, the ACC recommends that CMS consider whether the threshold should be adjusted at a state or regional level to ensure the increase does not negatively impact those areas substantially affected by extreme and uncontrollable circumstances.**

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Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

For CY 2021, CMS proposes to continue several policies from CY 2020 that align the Medicaid Promoting Interoperability program with the Merit-based Incentive Payment System (MIPS) Promoting Interoperability program including: aligning the eCQMs available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period; requiring that Medicaid EPs report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically; report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). **The continuation of these policies reflects CMS' commitment to reduce the reporting burden of participation in these programs and providing EPs with necessary reporting flexibility and program stability. The ACC appreciates these efforts by CMS.** Program and reporting stability are especially important during the COVID public health emergency when EPs, groups, and institutions should focus on caring for their patients.

MIPS Value Pathways (MVP)

In last year's proposed rule, CMS previously confirmed participation via MIPS Value Pathways (MVPs) would begin with the 2021 performance period. However, due to stakeholder feedback and the COVID-19 PHE, CMS will not be introducing MVPs into the program for the 2021 performance period. CMS is proposing to delay implementation of the MVP framework until the 2022 performance period or later. In the meantime, in this proposed rule, CMS is updating the five guiding principles and development criteria related to stakeholder engagement and transition to digital quality measures. Development of the MVPs will be undertaken with the foundation of the following principles:

1. MVPs should consist of limited, *connected complementary* sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, *align* scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; *MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.*
3. MVPs should include measures *selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included*, to encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.
5. *MVPs should support the transition to digital quality measures.* *

**italicized font indicates the proposed changes in the guiding principles*

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The ACC thanks CMS for the additional development criteria and guidance provided in the rule, for the proposed delay in MVP participation, and agrees with delaying implementation until at least 2022. Due to the current COVID-19 pandemic and the uncertainty about when it will end, the College believes physicians and the rest of the medical community will need additional support and time in adjusting when the pandemic is over. While some practices may be ready to resume normal patient flow and successfully resume MIPS participation fairly quickly, not all MIPS eligible clinicians will have this experience. Clinicians should have the option to move towards MVPs when they are adequately prepared (structurally, financially, administratively, or otherwise). **As such and despite the proposed Agency delay, the College continues to recommend a phased approach in the implementation of MVPs. The ACC believes that MVP participation should be voluntary and self-assigned, and clinicians should have the flexibility to participate at their discretion over the next few years.**

As reflected in previous comments, the College still believes a pilot period is necessary to help physicians and CMS understand the evolving reporting requirements and related necessary systemic changes that will derive from this new performance path. The ACC calls for pilot programs to test the validity of measures that will form the basis of MVPs. The pilot program could begin with a handful of specialties that report with the current set of available measures and activities. Test groups and individuals should be identified from various sites of services and should cut across all demographics, including small and rural practices. By implementing a pilot period, CMS will be able to gauge participation and reporting challenges or shortcomings. **The College believes it is possible to develop or identify measures that could result in valuable comparative data comparing a few MVPs, but believes that it may be challenging to identify measures that are comparable across all MVPs.**

Incorporating QCDRs and QCDR Measures into MVPs

The ACC supports the development of QCDR MVPs. Nevertheless, the ACC requests CMS consider the administrative and technical burden that is incurred in the development of MVPs, as well as the challenges already detailed in the letter associated with the full testing of QCDR measures. **The College requests CMS delay full testing of QCDR measures and subsequently QCDR MVPs, especially as the College anticipates CMS desires measures be fully tested prior to integration in the MVP reporting pathway.**

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MVP Development Criteria

In this proposed rule, CMS has provided guidance on utilization of measures and activities across Performance Categories and has provided questions to help shape the intent of measures and measurement. CMS has provided questions on appropriateness, comprehensibility, and patient voice to aid in development, as well. While the College is appreciative of this guidance and development criteria, the College also believes CMS should clearly outline processes in MVP candidacy and scoring before requiring clinician participation. The proposed rule states “CMS’ discretion [will] determine if an MVP is ready for inclusion in the upcoming performance period”. **The College believes there is still too much ambiguity in the development and approval of MVPs and believes a clear process and timeline for approving MVPs and new measures should be clearly delineated prior to implementation. Providing this information explicitly will ensure transparency is allotted to eligible clinicians and related stakeholders. The College urges CMS to release the standardized template for MVP candidates far in advance to MVP implementation.**

Alternative Payment Model Performance Pathway (APP)

In addition to further development of the MVP framework, CMS is proposing a new APM Performance Pathway (APP) reporting option in 2021 to align with this framework and facilitate transition of clinicians from MIPS to APMs. The goal of the proposed APP is to reduce reporting burden and focus on patient outcomes that align with the Meaningful Measures initiative. The APP would replace the current Merit-based Incentive Payment System (MIPS) Alternative Payment Model (APM) reporting requirements and create alignment with the proposed MIPS Value Pathway (MVP) system for all other MIPS participants. While the ACC supports the goals of the proposed APP, the College cautiously supports implementation of the APP as proposed.

Reduction in Quality Measures

The ACC cautiously supports the reduction in the number of quality measures APM participants are required to report as part of the APP. In addition to the CAHPS for MIPS survey and two administrative claims-based measures, participants would only report on three quality measures (*Diabetes: Hemoglobin A1c Poor Control; Preventive Care and Screening: Screening for Depression and Follow-up Plan; and Controlling High Blood Pressure*). Many of the existing measures related to immunization and screening currently reported through the CMS web interface would no longer be required.

The ACC supports the move to reduce administrative burden, focus on key areas of performance and create a better focus on improving patient care. **However, we urge CMS to continue monitoring both performance and outcomes while planning to introduce additional or new measures, if necessary, in future years.** The APP measure set will be applied to broad population-based APMs. CMS must ensure

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that this limited set of measures captures outcomes across an entity's patient population and that performance in other areas of care does not drop due to the elimination of measures.

Elimination of the CMS Web Interface in 2021

The ACC recommends that CMS delay the sunset of the web interface reporting option by one performance year to PY 2022. The web interface has been the reporting mechanism for Medicare Shared Savings Program (MSSP) participants as well as many MIPS participants. While the ACC supports the move to eliminate this reporting option in favor of providing entities with more flexibility for reporting, the College believes that keeping the web interface for one additional year can provide stability as participants transition to new reporting processes. Many sites may not have the capability to explore other reporting mechanisms at this time due to financial and staffing constraints caused by the COVID-19 PHE.

In addition, the ACC requests more clarity on quality reporting for the Next Generation ACO program which relies on the CMS web interface. CMS has extended this model for one additional year; the proposed rule does not indicate whether Next Generation ACO participants would have to transition to a new reporting method for the final year of the program or if they will be permitted to use the web interface for one additional year. The ACC requests that clarification be provided to model participants and noted in the final rule.

Phase-In of APP

CMS proposes to require the APP for all MSSP ACO participants and provide it as an option for MIPS APM participants starting with the 2021 performance period. **The College appreciates that for the first year, CMS will provide all participants voluntarily utilizing the APP with an automatic 100 percent MIPS Quality score. However, the ACC asks that CMS consider the impact of the COVID-19 PHE on the timing of implementation for MSSP ACOs and offer a similar voluntary transition period.**

The phase-in for voluntary participants will allow entities to implement a new reporting mechanism with the elimination of the web interface and provide a year of data collection so that sites can assess their performance against the consolidated core measure set. Applying a phase-in period for all APM participants would also protect entities against any potential negative impacts experienced due to the COVID-19 PHE. Early in the pandemic, many patient visits had to be delayed and rescheduled as practices reworked their processes to reduce the risk of exposure to staff and patients. Some practices are currently beginning to resume normal patient flow as they have been able to successfully implement telehealth measures and new scheduling protocols to allow patients back into offices. Entities are just starting to assess the impact of rescheduled care and the patient-driven fear of going to a medical office during the pandemic on quality measure performance. Implementing a phase-in for all participants would allow entities to adjust to the new APP reporting system and establish historical

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benchmarks against the new measure set in a year where participants are more prepared to address the impact of the pandemic.

Days at Home Measure

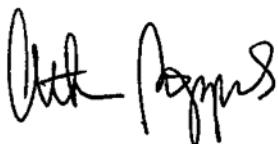
For future years, CMS is considering the addition of a Days at Home measure to the APP core measure set. **The ACC cautiously supports this concept and looks forward to the opportunity to provide further comment on the specific measure once it is developed.** The Days at Home measure would assess participants on the number of days spent outside the hospital as an inpatient, in observation, or in a post-acute care setting. If designed appropriately, this measure could incentivize participants for managing the care of patients and keeping them out of the hospital while balancing the current measure that penalizes participants for readmissions.

As with all measures, the ACC recommends that this measure is thoroughly vetted and tested before it is implemented into the APP for accountability purposes. The College urges CMS to consider the impact of factors such as the type and/or number of chronic diseases patients may have, geographic trends, sociodemographic status, and patient and caregiver health literacy on the ability of participants to control performance under this measure. **The ACC recommends that CMS introduce this measure through a pilot period or implement a reporting only period so participants can establish a benchmark for performance before the measure is used for scoring purposes.**

Conclusion

The ACC appreciates the opportunity to comment on the CMS notice of proposed rulemaking regarding the CY 2021 Medicare Physician Fee Schedule. The ACC looks forward to collaborating with CMS to further develop meaningful approaches and pathways to promote a healthy physician environment and quality patient care. The ACC urges CMS to consider the recommendations detailed in this letter. Should you or your staff require additional information or clarifications, please contact Claudia Vasquez, Associate Director of Medicare Payment & Quality Policy, at cvasquez@acc.org.

Sincerely,



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