



September 13, 2021

The Honorable Chiquita Brooks-LaSure
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 2022 Payment Policies Under the Physician Fee Schedule
and Other Changes to Part B Payment Policies; Medicare Shared Savings Program
Requirements; Provider Enrollment Regulation Updates; Provider and Supplier
Prepayment and Post-Payment Medical Review Requirements

Submitted via www.regulations.gov

Dear Administrator Brooks-LaSure:

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.

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. 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:

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*The mission of the American College of
Cardiology and the American College
of Cardiology Foundation is to transform
cardiovascular care and improve heart health.*

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I. Physician Fee Schedule

A. Refinements to Current Policies for Split or Shared Evaluation & Management Visits

After withdrawing previously existing manual provisions for billing split (or shared) visits and considering the role updated CPT E/M Guidelines could play in clarifying policy issues that may arise in the context of split (or shared) visits, CMS proposes updates in regulation to determine who may bill for split (or shared) visits. CMS proposes to define a split (or shared) visit as “an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group.” Under the withdrawn manual provisions, it had previously been CMS policy that the physician may bill for a split (or shared) visit only if they perform a substantive portion of the visit, and the practitioners must be in the same group and furnishing the visit in specified settings in order to bill for a split (or shared) visit.

The manual also limited billing for split (or shared) visits to services furnished to established patients. CMS also proposes to modify policy to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility /Nursing Facility (SNF/NF) E/M visits.

i. Definition of Substantive Portion

Noting that the prior manual provisions included few and possibly conflicting definitions for what constitutes a “substantive portion” of a split (or shared) visit, CMS proposes to define in new regulation that the “substantive portion” be defined as “more than half of the total time spent by the physician and non-physician practitioner performing the visit.” Additional proposals about how to count the “distinct time” of two clinicians and which activities count toward “qualifying time” follow. The ACC agrees that relying on time in this manner to determine which clinician should bill for a split (or shared) visit may be convenient in some instances but cautions CMS from finalizing this proposal as written. The parameters CMS proposes around use of time to identify the “substantive portion” seem reasonable to use in instances when clinicians *choose* to bill using these time-based parameters. (Though the Agency should also be open to adjustment as experience is gained with the constructs of “distinct time” and “qualifying time.”)

However, it would be incorrect to *universally* require that *only* a clinician who spends more than half of the total time with the patient could bill for the service. Such a requirement presumes that all time is equally weighted when it comes to patient care, and that is not the way facility patient care works. While CMS notes the ability of clinicians to choose an E/M visit level by medical decision making (MDM) and the difficulty of attributing MDM to a single clinician because MDM is not necessarily quantifiable and can depend on patient characteristics, in many instances it would still be more accurate for the clinician executing a *majority* or *critical element* of MDM to bill for a split (or shared) service. As an analogy, it would not make sense to suggest an airline pilot should not be paid for her work with the critical portions of communicating with the tower, taking off, navigating a route, landing, and steering to the gate because she also relied on autopilot for more than half of the flight time in the air and shared responsibilities with the co-pilot. Ultimately, this proposal serves to reduce the concept of “team-based care” by forcing clinicians to separate their time with patients. This proposal goes against the ACC’s core principle of having all members of the cardiovascular team working together for the patient.

ii. Definition of Same Group

The ACC is concerned that defining—or not defining—a group is not as simple as it may appear in the proposed rule, as it could have downstream consequences for MIPS, cost measurement and other programs that rely on PECOS designation for attribution purposes. An example that shows current understanding of the proposal and possible consequences may be illustrative.

If a nurse practitioner (NP) in a cardiologist’s group spends 20 minutes with a patient while the cardiologist spends 10 minutes with the patient, the NP would bill for that encounter because the NP is part of the same group and spent the majority of the time with the patient on the day of the

encounter. Under this care model, the NP is working with the cardiologist as part of a specialized team providing cardiovascular care. However, since every NP is classified as a “primary care provider” under PECOS, the NP’s encounter may be considered a primary care service.

If a group is defined as “clinicians in the same TIN,” then many non-cardiology physicians and NPs could be in the same group as cardiologists. However, due to current attribution methodologies, the NP’s “primary care” encounters may create an instance where the group is attributed as a patient’s primary care provider and cause an over-attribution of all patient’s care to that cardiology group under measures such as Total Per Capita Cost. If group means “clinicians in the same TIN with the same PECOS specialty designation,” then the NP in the above scenario would not count as the same group because there isn’t a specialty designation available for NPs.

CMS should evaluate any impact this proposal may have on specialty-based risk-adjustment methodologies used under cost measurement and other payment and quality programs to ensure that it does not result in any artificial over-attribution or deflation of risk-adjusted performance or payment due to the PECOS structure and current attribution methods.

The ACC recommends CMS defer implementation of new policy and elements regarding split (or shared) billing so that medical societies can work with on a proposal to the CPT Editorial Panel that addresses these and other questions posed in the rule through clarification of the CPT Guidelines CMS references. This would have the desirable outcome of clinicians having a single and consistent set of guidelines it can follow for all payers when reporting their services.

The ACC supports CMS’ proposals to allow split (or shared) visits to be billed for both new and established patients, and for critical care and certain SNF/NF E/M visits. However, the **ACC does not support CMS’ proposal to create a modifier to describe split (or shared) visits at this time.** Such a modifier would create a new administrative burden when the new CPT E/M coding structure and guidelines have sought to reduce administrative burden.

B. Clinical Labor Pricing Updates

CMS proposes to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update. CMS believes it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. The clinical labor rates were last updated in CY 2002. The College agrees that the 20+ year-old Medicare physician fee schedule (MPFS) clinical labor rates should be updated. However, our initial analysis shows updating the clinical labor rates is estimated to increase Medicare direct practice expense costs by 30%. Based on \$11.5 billion in Medicare allowed practice expense direct costs, we estimate the “price tag” for updating the clinical labor rates in CY 2022 will be approximately \$3.5 billion. Due to budget neutrality constraints, the CY2022 scaling factor to account for this dramatic rise in direct practice expense costs is proposed to fall drastically to

0.44, from 0.59, an unprecedented rate. The result is that the burden of the offset is disproportionately distributed within the MPFS and rests squarely on the services performed in the nonfacility office setting for services with high supply and equipment costs. If the CMS proposal goes into effect, as written, many of these nonfacility offices will fail. This will limit access to care for Medicare patients and force those patients into the facility-based system at a significantly higher cost to Medicare and to patients.

Office-based care is cost effective. Medicare charges are often significantly higher in the hospital setting than in the nonfacility office-based setting. The patient copay is also often higher in the hospital setting. Office-based care is efficient. It is easier for patients and their families to navigate than a hospital. Continuity of care is easier to achieve in an office setting because the patient-practice and patient-doctor relationships are maintained. During this public health emergency, we have seen that receiving care in the office limits the number of interactions that patients have with medical and nonmedical personnel and minimizes exposure to COVID and other illnesses. It also allows a reduced number of hospital staff to focus on sicker patients, which we have seen is critically important during a public health emergency like COVID-19.

Cuts to specialties under the fee schedule would diminish the healthcare system's ability to provide ongoing patient care and would complicate response to the ongoing COVID-19 pandemic. Throughout the public health emergency, it has been critical that hospitals be able to focus on the sickest pandemic patients. However, many other diseases such as cardiovascular patients with cardiac symptoms or peripheral artery disease must still be addressed. Office-based care provides a critical site-of-service outside of the hospital to deal with non-COVID cases so hospitals can focus on a resurging pandemic. Payment cuts to physicians threaten the viability of critical office-based setting during the COVID-19 pandemic and beyond.

i. Scaling Factors

The direct scaling factor is proposed to decrease -24% from 0.5916 in 2021 to 0.4468 in 2022. The practice expense component of the MPFS comprises approximately 45% of the total physician payment and that percentage is fixed. Therefore, an increase in the clinical labor rates results in a shift of RVUs that were previously directed to supplies and equipment. Stated another way, Medicare will now reimburse 44 cents on the dollar instead of 59 cents on the dollar for supply and equipment costs. An unsustainable payment rate for any business. The services by the ACC and others in the House of Medicine often require the use of expensive supplies that need to be stocked and readily available. The services also often require considerable capital costs to purchase and maintain equipment. It is reckless for CMS to propose a policy that would result in such a wildly fluctuating shift in reimbursement. The Medicare system should provide stable and predictable reimbursement for care rendered to their beneficiaries. **CMS should explore options to adjust the scaling factor(s) in order to more appropriately reimburse for expenses incurred to treat their beneficiaries.**

ii. Budget Neutrality

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality. This \$20 million "threshold" has been the same since the inception of the MPFS in 1992. No adjustments to this threshold have been made to account for new technology over 30 years. As stated previously, allowed charges would increase by approximately \$3.5 billion if the clinical labor proposal was implemented in 2022 without any offsetting reduction to the direct practice expense scaling factor. **CMS should analyze the effects of implementing the clinical labor rates as they have proposed, after no change for 20 years, versus having implemented those updates more regularly. CMS should publish how the annual \$20 million restriction on changes to expenditures could have played a role in the clinical labor updates. CMS should also consider all the ways budget neutrality can be accounted for in the practice expense methodology, as there are several steps in the formula where budget neutrality is applied.**

iii. Transparency of Impact

By increasing the clinical labor pricing, physician services with high-cost supplies and equipment are disproportionately impacted by the budget neutrality component within the practice expense relative values. In the proposed rule, CMS displayed the isolated anticipated effects of the clinical labor pricing update on specialty payment impacts in Table 6. CMS highlights in the text that specialties with a substantially lower or higher than average share of direct costs attributable to labor would experience significant declines or increases, respectively, if this proposal is finalized. The Agency goes on to say that the Table 6 impacts do not include complete impacts of all the policies the Agency is proposing for CY 2022, only the anticipated effect of the isolated clinical labor pricing update. The impacts published in Table 6 and Table 123 are misleading. For example, the highest negative impact in Table 123 is -9% and in table 6 is -10%. In reality, the negative impact is much greater. As described above, this proposal disproportionately hits those services that are incurring the most direct practice expense. More specifically, groups of similar services in the nonfacility setting are projected to incur **reductions greater than -20%** for the majority of their services. While the College understands the impact tables are for illustrative purposes for aggregate impacts on specialties, and not meant to be code specific, it would be more transparent to share actual impacts when they are so devastating to providers of office-based procedures with high supply and equipment costs. **CMS should publish a cost estimate for the clinical labor proposal as well as impacts to illustrate how the proposal is actually impacting nonfacility reimbursement rates for highly affected code families.**

iv. Clinical Labor Rates – BLS Data

CMS believes it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. CMS is proposing to use the methodology outlined in the CY 2002 PFS final rule, which draws primarily from United States Bureau of Labor Statistics (BLS) wage data. CMS believes that the BLS wage data continues to be the most

accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS.

The clinical labor rates were last updated in CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available. In the proposal, 12 of the 32 staff types used “other sources” instead of BLS data for pricing. These 2002 “other sources” data were not readily available for public review. For CY 2022, 14 of the 32 staff types are being updated using a BLS crosswalk because an exact match was not available. To maintain transparency, **CMS should publish the ‘other sources’ wage data details. In addition, CMS should update specific clinical labor wage rates based on stakeholder comments and data.**

v. Data Elements in Wage Rates

The BLS data includes several data elements for consideration. In the clinical labor pricing update proposal, CMS utilizes the mean wage data to establish updated clinical labor rates, while the majority of the MPFS data inputs are based on the median. For example, when developing RUC recommendations (work and practice expense) the physician times, work RVUs, clinical staff times and clinical staff types all use medians (i.e., “typical”). The BLS survey data also include wage rates for a variety of sites of service (e.g., hospitals, physician offices, farms) and wage data from a variety of industries. **The ACC urges CMS to consider using the median wage data, instead of mean wage data, to more accurately capture typical wage rates and to be consistent with the median statistic used for clinical staff time.**

vi. Fringe Benefit Multiplier

To account for employers’ cost of providing fringe benefits, such as sick leave, CMS proposes to use the same benefits multiplier of 1.366 that was utilized in CY 2002. Using the fringe benefits multiplier rate from 20 years ago (2002) is not consistent with CMS’ premise for updating the clinical labor pricing which was to “maintain relativity with the recent supply and equipment pricing updates”. BLS publishes benefits data routinely. **CMS should use a current fringe benefits multiplier ([1.296 BLS](#)).**

vii. Timeline

The current clinical labor proposal requires additional analysis and modifications prior to implementation. There is further work to be done by both the Agency and stakeholders to ensure accurate data is used and appropriate methodological steps are taken for implementation. **The Agency should delay this update until an evidence based on updated information can be evaluated.** It is important to note that CY2022 will be the 4th and final transition year of the update to supply and equipment items. A proposal that also yielded significant shifts in payment rates. **CMS should not implement this update for CY2022 and instead should consider comments and publish an updated clinical labor proposal.**

In addition, CMS has requested comment on whether to implement a four-year transition to the new clinical labor cost data. There is precedent for a phased transition for significant MPFS changes, across several calendar years. CMS utilized a 4-year transition for the market-based supply and equipment pricing update concluding in CY 2022. CMS also utilized a 4-year transition, starting in 2010, for the practice expense proposal resulting from the Physician Practice Information Survey (PPIS). **CMS should use a 4-year transition to implement an updated clinical labor proposal if/when any budget-neutral changes are implemented.**

viii. Summary of Recommendations

The ACC advocates for cost effective, efficient and safe healthcare. The clinical labor proposal, as written, if implemented, will jeopardize the delivery of care to Medicare beneficiaries. We recommend CMS take the following steps regarding the clinical labor proposal:

1. Explore adjustments to the scaling factor(s)
2. Analyze the budget neutrality options
3. Publish non-BLS ‘other sources’ wage data
4. Update specific clinical labor wage rates based on stakeholder comments and data
5. Consider the use of median wage rates
6. Apply a more current fringe benefits multiplier
7. Analyze and publish codes with the most significant impacts
8. After modifications and an updated proposal, utilize a four-year phase-in

C. Telehealth and Other Services Involving Communications Technology

i. Remote Direct Supervision for Cardiovascular Rehabilitation

The proposed rule invites comments on whether flexibilities granted during the COVID-19 PHE allowing remote direct supervision of cardiac and pulmonary rehabilitation services should extend beyond December 31, 2021 or the end of the calendar year in which the PHE ends, whichever is later.

In the proposed CY 2021 Hospital Outpatient Prospective Payment regulation, CMS proposed that direct supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services could be met virtually without requiring the physician’s physical presence in that location. The rationale provided by CMS explained that this would continue to improve access for patients and reduce burden for providers after the end of the public health emergency (PHE). Virtual presence would be met through audio/video real-time communications technology (excluding audio-only), subject to the clinical judgment of the supervising physician.

CY 2021 final regulations under PFS and HOPPS made two significant changes:

1. Aligned the definitions of virtual direct supervision under the PFS (410.32) and OPPTS (410.27). This provided clarity and consistency, allowing for practical application of this option.
2. Modified the proposed permanent status of virtual direct supervision from permanent to expiring at the end of the year that the public health emergency (PHE) expires. This was done to reconsider any potential negative impact of virtual direct supervision on the quality of pulmonary, cardiac, and intensive cardiac rehabilitation services.

COVID safety protocols have severely limited and continue to limit patient access to pulmonary, cardiac, and intensive cardiac rehabilitation services. The inclusion of direct supervision via virtual presence has improved access for patients during the PHE. It has allowed the relocation of pulmonary, cardiac, and intensive cardiac rehabilitation services from the hospital to satellite locations where there is not an MD or DO physically available. Rural and critical access hospitals (CAHs) have benefited from the direct supervision waiver by allowing the expansion of program hours as these services cautiously and gradually re-open to full capacity *without* the restriction of a physician required to be *physically* available to serve in the direct supervision role. This flexibility has also benefitted these rehabilitation patients throughout the nation, regardless of geography, through enhanced access to care that should be permanently implemented in CY 2022 rulemaking.

The following information addresses comments submitted by others following the proposed permanent status for virtual direct supervision. Questions about safety and oversight were raised by some commenters in response to the CMS consideration of virtual direct supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services.

Beneficiaries begin a cardiac, intensive cardiac, or pulmonary rehabilitation program with the development of an individualized treatment plan (ITP) with the patient. This includes an initial assessment and exercise prescription that is reviewed and signed by the medical director.

The safety of pulmonary rehabilitation has been well-substantiated. Rates of reported adverse events are very low at 0.4%.¹ Data demonstrating low rates of serious cardiovascular events in cardiac rehabilitation go back to the 1980s. Findings from three well-known studies are as follows:

- 1 cardiac arrest per 111,996 patient-hours, 3.4 myocardial infarctions per 293,990 patient-hours, 1 death per 783,972 patient-hours²

¹ Puhan MA, Gimeno-Santos E, Cates CJ, Troosters T. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2016 Dec 8;12(12):CD005305. doi: 10.1002/14651858.CD005305.pub4. PMID: 27930803; PMCID: PMC6463852.

² Van Camp SP, Peterson RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. JAMA. 1986 Sep 5;256(9):1160-3. doi: 10.1001/jama.256.9.1160. PMID: 3735650.

- 1 event per 49,565 patient-hours of exercise training³
- In higher-risk patients with heart failure, there were similar rates of adverse safety events in patients randomized to cardiac rehabilitation, compared to patients randomized to usual care.⁴

CMS previously stated it intends to monitor the use of interactive audio/video real-time communications technology to meet the direct supervision requirement through the PHE. The professional societies believe it will be evident that the quality and safety of pulmonary, cardiac, and intensive cardiac rehabilitation services are not negatively affected and, in fact, access to these services is improved with a virtual option for direct supervision. **The ACC supports CMS finalizing its proposal from 2021 rulemaking that the definition of “direct supervision” at § 410.32(b)(3)(ii) to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation after the PHE for COVID-19.** If the Agency is uncomfortable with that possibility, even extending it until December 31, 2023 as some telehealth flexibilities are proposed would be a helpful intermediate step. This would allow additional time for practice and study to evolve and allow for further extension or a permanent change in the future.

The Agency also seeks comments on whether a service level modifier should be required to identify when requirements for direct supervision were met using appropriate remote technology. **The ACC is generally cautious to support new requirements for coding and documentation when they may not be necessary and does not believe a need exists at this time.**

ii. Revised Timeline Services Temporarily Added to the Telehealth List

The ACC supports the proposal to extend coverage of services that were added to the Medicare telehealth list on an interim basis in response to the COVID-19 PHE until the end of 2023 and urges that it be finalized. Additional services that were added to the telehealth list during COVID-19, especially the three codes for telephone evaluation and management services and cardiac rehabilitation services, should be included in the category of services which are proposed to remain on the telehealth list through 2023. As mentioned above in the context of cardiac rehabilitation services, the ACC continues to recommend that the current policy during the COVID-19 PHE allowing “direct supervision” to include immediate availability through the virtual presence of the supervising physician using real-time, interactive audio/video communications technology should be made permanent.

³ Pavy B, Iliou MC, Meurin P, Tabet JY, Corone S; Functional Evaluation and Cardiac Rehabilitation Working Group of the French Society of Cardiology. Safety of exercise training for cardiac patients: results of the French registry of complications during cardiac rehabilitation. Arch Intern Med. 2006 Nov 27;166(21):2329-34. doi: 10.1001/archinte.166.21.2329. PMID: 17130385

⁴ O'Connor CM, Whellan DJ, Lee KL, Keteyian SJ, Cooper LS, Ellis SJ, Leifer ES, Kraus WE, Blumenthal JA, Rendall DS, Miller NH. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA. 2009;301:1439-50.

The ACC disagrees with the CMS proposal to limit Medicare telehealth coverage for the many services listed in Table 11 to the end of the PHE instead of extending coverage through 2023 as is proposed for the services currently included in Category 3. Since all these services have only been covered when provided via telehealth during the COVID-19 PHE, there has not been any experience to date with their telehealth utilization in Medicare outside the context of the PHE. As with the services that are already included in Category 3, **CMS should allow time beyond the PHE for experience and evidence to be developed regarding telehealth use of the Table 11 services in clinical care and extend coverage for these services through 2023.** Since the goal of Category 3 is not to make a permanent decision about a code but to allow time for information to be assembled, there is no reason to not allow that time. It is problematic for CMS to require that the evidence be provided to indicate that codes should be permanently added to the telehealth list right now when the clinicians and hospitals whose patients may be most likely to benefit from the policy are not easily able to provide the requisite data, especially as COVID-19 cases are rising in these communities due to the Delta variant.

D. Valuation of Specific Services

i. External Cardiovascular Device Monitoring

CMS disagrees with the RUC-recommended work RVU of 0.52 for code 93228 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*) and proposes a work RVU of 0.43, based on an intra-service time ratio between the code's current and RUC-recommended intra-service times ($0.43 = ((10 \text{ minutes}/12 \text{ minutes}) * 0.52)$). CMS notes that it proposes "...a work RVU that accounts for decrease in total time to provide this service, given that the increased tracings and daily reports are offset by the efficiencies gained by technological advancements." However, the work RVU proposed by CMS is a reduction of 17 percent, whereas the total time only decreased by 8 percent, rendering the statement inaccurate. It is unclear what rubric CMS relies on to determine when to rely upon intra-service time ratios versus total time ratios.

CMS' proposed value would assign a work intensity that would be inappropriately low for any physician service. The physician work intensity of CMS' proposal is a small fraction of the work intensity for the top two key reference codes. In addition, the assigned intensity by CMS would be dramatically lower than the one assigned to a Level 1 established patient office visit (99211), which does not even require the presence of a physician or other QHP, producing a massive rank order anomaly.

The ACC would like to remind CMS of both the Agency's and the RUC's longstanding position that treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only

certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. In many scenarios, CMS selects an arbitrary combination of inputs to apply, including total physician time, intra-service physician time, “CMS/Other” physician times, Harvard study physician times, existing work RVUs, RUC-recommended work RVUs, work RVUs from CMS-selected crosswalks, work RVUs from a base code, etc. This selection process has the appearance of seeking an arbitrary value from the vast array of possible mathematical transformations, rather than seeking a valid clinically relevant relationship that would preserve relativity. The ACC is increasingly concerned that CMS is eschewing the bedrock principles of valuation within the RBRVS (namely, magnitude estimation, survey data and clinical expertise) in favor of inconsistent, arbitrary mathematical formulas.

When physician times are updated in the Medicare payment schedule, the ratio of intra-service time to total time, the number and level of bundled post-operative visits, the length of pre-service and length of immediate post-service time may all potentially change for the same service. These changing components of physician time result in the physician work intensity per minute often changing when physician time also changes. CMS should always account for these nuanced variables.

CMS noted that 0.43 is also the same value as reference code 93290 *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; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors* (work RVU= 0.43, intra-service time of 10 minutes, total time of 23 minutes) and notes that both services involve the same amount of physician time. However, one issue with this reference code is 93290 is only performed alone 5 percent of the time, often being performed in parallel to separately reported pacemaker interrogation and wearable defibrillator interrogation service. In addition, this reference code is performed almost half the time with an office visit, whereas 93228 is performed only 13 percent of the time in conjunction with an office visit. Unlike the reference code, 93228 is typically performed without any separately reported services. The reference code is a less intense service performed in conjunction with other services making it a poor comparator; these distinctions between the two services support the RUC recommendation for 93228.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to top key reference code 93298 *Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional* (work RVU= 0.52, intra-service time of 7 minutes, total time of 17 minutes) and MPC code 76519 *Ophthalmic biometry by ultrasound echography, A-scan; with intraocular lens power calculation* (work RVU= 0.54, intra-service time of 10 minutes, total time of 22 minutes). While technology has advanced to negate some low intensity work and making review and management of data more efficient, the RUC-recommended RVU accurately reflects the average wear time increasing from 14 to 20 days, the number of ECG tracings, as

well as the increasing daily reports. **The ACC urges CMS to accept a work RVU of 0.52 for CPT code 93228.**

CMS seeks additional information about the acquisition costs for equipment item EQ340 *Patient Worn Telemetry system*. These devices, which have experienced substantial improvements in technology since 2008, are proprietary devices owned and manufactured for each of the independent IDTFs. Only the independent IDTFs or the device manufacturer would be able to provide this information. The ACC worked to obtain accurate information about practice expense inputs during the RUC process and suggests CMS may find additional information in that submission or in supplementary information submitted by monitoring vendors. The ACC has encouraged those stakeholders to share that type of additional, proprietary information with the Agency. **The ACC urges CMS to accept the direct practice expense recommendations for codes 93228 and 93229.** The ACC worked with the RUC to provide additional responses on specific proposed refinements, such as the role of a senior technologist for quality assurance, and that information has been submitted separately. Societies collaborated with providers of 93229 to collect and present the best available information to inform PE inputs. Part of that collection was two separate training/process documents the Agency may not have noted in the original submission. File "05d MCT Process Manual 1" explicitly describes the role of a "Senior Monitoring Technician" on page 3. To the best of our knowledge, that is the same activity The Moran Company described as typical on page 5 of their report and was the basis of this 24-minute recommendation. We recommend CMS restore those efforts, and also encouraged providers to share additional information about the use/role of a second, senior tech for quality assurance.

ii. Electrophysiologic Evaluation Left Atrial Pacing

CMS proposes a work RVU of 1.50 for 93621 *Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)*. The ACC supports the RUC-recommended work RVU of 1.75. The RUC chose a crosswalk to CPT code 36483 *Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)*, a value below the survey 25th-percentile work RVU. CMS is basing its proposal on a crosswalk to CPT code 16036 (*Escharotomy; each additional incision*). CMS states that CPT code 16036 is also an add-on code for a surgical incision that shares both an identical intraservice work time and a total time of 20 minutes with CPT code 93621, believing that the code has a similar intensity to 93621. **The ACC disagree with CMS' decision to crosswalk 93621 to 16036.** The crosswalk that the RUC agreed upon was based on discussions among the RUC reviewers and accounted for similarities between services that both rely upon catheters to execute complex maneuvers inside the cardiovascular system. CMS' proposed crosswalk is problematic because the service is completely different from cardiac procedures. Also, 16036 can be billed multiple times. The

RUC-recommended crosswalk is a cardiovascular procedure; and carries similar intensity of work. The ACC recommends CMS reconsider this proposal and **accept the RUC-recommended value of 1.75 work RVUs.**

iii. Cardiac Ablation Services Bundling

This family of codes came under review when CPT code 93656 *Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right ventricular pacing/recording when necessary, and His bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation* triggered a RUC screen for high volume growth. In responding to that screen, societies determined that the services have changed since the codes were originally valued and it was appropriate for additional work performed together with 93656 and 93653 more than 90% of the time to be bundled. In October 2020, the CPT Editorial Panel revised one code (93653) to bundle with 3D mapping and to include “induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus,” and another (93656 *Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right ventricular pacing/recording when necessary, and His bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation*) to add 3D mapping and “left atrial pacing and recording from coronary sinus or left atrium” and “intracardiac echocardiography including imaging supervision and interpretation” to their descriptors.

In considering this topic, it is important to keep in mind the clinical value ablation services offer to patients. Ablation has been shown to improve patient’s quality of life and decreases hospitalizations and mortality, particularly in patients with heart failure. It also has been shown to improve patient outcomes when performed early. Significant healthcare resources are conserved through avoidance of complications, such as stroke, myocardial infarction, tachycardia, and heart failure. Dramatic reductions in payment could reduce the number of physicians offering ablation services, result in longer wait times for procedures at sites that may be farther away, and even mean that some patients may not be offered ablation therapies at all.

As CMS notes in the proposed rule, surveying societies had concerns about the reliability of the results of the work RVU survey that were presented in January 2020, the last meeting of the 2022 CPT/RUC cycle. The significant reduction in time made it seem unlikely that survey respondents correctly accounted for the bundling of additional work into 93653 and 93656. That could have occurred because the same code numbers were used in the survey, but respondents would already be familiar with the longstanding codes that did not bundle additional work. The societies and the RUC worked to develop interim recommendations with a plan to resurvey the codes with “dummy” codes and some additional instructions for reading instructions for the April 2020 RUC meeting.

CMS based its proposals on the January 2020 survey data and recommendations. As CMS had not yet reviewed the April 2021 RUC recommendations, the Agency is proposing to maintain the current physician times and current work RVUs for codes 93653, 93654, and 93656 for CY2022. **The ACC urges CMS to implement the April 2021 RUC recommendations for physician work and practice expense for this family in 2022 that have been previously submitted by the RUC.** These recommendations were based on survey data from the second survey, discussed vigorously by the RUC, bolstered by comparisons to other services in the fee schedule, and in many ways are similar to the first survey for the January RUC meeting, supporting reliance on these survey-based recommendations.

As 93653 and 93656 have been extensively revised to newly bundle work that was previously separately reported, maintaining the current times and values for these services is not appropriate. CMS indicates it proposed to maintain current times and work RVUs until additional and more accurate information could inform valuation. This suggests the Agency sought to hold these services “harmless” while the additional survey and recommendations were developed. If CMS is unable to consider the April 2021 RUC recommendations for implementation in 2022 through the notice and comment process, it would need to combine with times and RVUs of 93653 (14.75) with 93613 (5.23) and 93621 (1.75*) to achieve that outcome. That would be a 2022 work RVU for 93653 of 21.73. Similarly, a stable work RVU for 93656 would combine the current RVU (19.77) with 93613 (5.23) and 93662 (1.44) for a 2022 work RVU of 26.44. **If CMS is unable to digest the April RUC recommendations and implement them for the final rule, the ACC recommends values that include the work of the newly bundled services as a first alternative.**

Further, the ACC recommends that should reductions of the proposed or similar magnitude be finalized, CMS make an exception to its policy that phase-in of reductions of greater than 20% is limited only to codes that have undergone no changes in descriptor, and instead phase in such a reduction over two years. This recommendation applies whether CMS were to finalize its proposed values, the April RUC-recommended values, or something else that produces bundled reductions of greater than 20%. Phasing in reductions when bundling of multiple services into a single code that produces reductions of greater than 20% aligns with the spirit of that policy. For practices and physicians, it does not matter that the code descriptor was changed. They would simply see a reduction from 21.73 work RVUs to 14.75 work RVUs for 93653 and from 26.79 to 19.77 work RVUs for 93656. Each of these reductions exceeds 20%. It would moderately mitigate the negative impacts to practices of significant drops in work RVUs and give them additional time to prepare for workflows and logistics to best meet patient care needs in the face of declining revenue.

For other codes in this group, CMS proposes work RVUs for add-on codes 93655 *Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)* and 93657 *Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial*

fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure) that are lower than the January RUC recommendations on which it based its proposals. These values are also below the April RUC recommendations the ACC recommends CMS adopt. The work of performing subsequent ablations is due the patient having complex arrhythmia that requires identifying additional foci to alleviate arrhythmia. The proposed values do not reflect the intensity of that work. The intensity increases when additional lesions are given. There is a fatigue factor, ongoing anesthesia (and hence more risk), and increasing edema from the original ablation that make access to additional target sites more problematic. Mapping can become much more problematic, in addition to the fact that the left atrial catheter may have to be repositioned multiple times during the process. The same additional elements that were bundled into the base codes because they are now inherent to the ablation procedures—3D mapping, left atrial pacing, intracardiac echocardiography—are also performed during the respective add-on procedures.

In the January 2021, the RUC recommended an interim value of 6.50 RVUs through a crosswalk. In the survey reviewed in April 2021, the survey data resulted in a 25th percentile of 7.00 work RVUs for 93655 and 93657. As stated above, the intensity of the work has remained if not increased due to the broader population of eligible patients. Patients who receive the add-on services typically are in a more complex disease state thus adding to the services' intensities. Decreasing the values to 5.50 discounts the supported data of two surveys. Finally, the crosswalks recommended for the add on procedures are not cardiac. The ACC is concerned that a service with identical service times was selected because it has a lower work RVU, not because it appropriately approximates the skill, risk, intensity, and complexity of the work of performing additional ablation procedures by magnitude estimation. **The ACC recommends implement the RUC-recommended values of 7.00 RVUs for CPT codes 93655 and 93657.**

iv. 3D Imaging of Cardiac Structures

The ACC supports CMS' proposal to implement the RUC-recommended work RVU of 0.50 for new code 93XX0 *3D echocardiographic imaging and postprocessing during transesophageal echocardiography, or during transthoracic echocardiography for congenital cardiac anomalies, for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, interatrial septum, interventricular septum) and function, when performed (List separately in addition to code for echocardiographic imaging)*. While proposing no refinements to this codes PE, the Agency does inquire whether an invoice submitted with relevant materials for a 3D probe reflected both the probe *and* the base echocardiography machine or simply the probe itself. The ACC reviewed the submitted invoice and is able to confirm the price of \$31,754.30 is for the probe itself, not any other equipment.

v. Cardiac Catheterization for Congenital Defects

In May 2020, the CPT Editorial Panel replaced a family of four cardiac catheterization codes with five new codes to describe cardiac catheterization for congenital cardiac defect(s). In addition, the Panel replaced two cardiac output measurement codes with one new add-on code to

report cardiac output measurement(s), performed during cardiac catheterization for congenital cardiac defects.

CMS did not address the submitted compelling evidence that supports increases for these services. CMS dismisses the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. CMS only proposes blanket reductions instead of considering how a service may have changed or increased. **The ACC requests that CMS address the compelling evidence that was submitted with the RUC recommendations when the agency does not accept the RUC recommendation. Here is the compelling evidence argument for CMS' consideration:**

The RUC reviewed and agreed that there is compelling evidence based on a change in the patient population and a change in technology. The specialty societies noted, and the RUC agreed that most diagnostic catheter studies were performed in children who were healthier with simpler cardiac defects when the previous code structure was last valued in 1997; children with more significant cardiac defects had no treatment options, so catheterization was not warranted. Over the past 23 years, as result of improvements in both technique and technology, the specialty has evolved and now performs a substantially larger number of more complex diagnostic evaluations to guide more complex interventional procedures, and the typical patient is now a more complex patient requiring more pathology. The specialties noted that one of the whitepapers that they provided by Nicholson et al. confirms that these procedures were unable to be previously accomplished on the current typical patient with earlier technology/techniques. The specialties provided additional literature to further demonstrate the changes in congenital catheterization over the past two decades.

The specialties noted that, relative to adult patients with normal cardiac anatomy, the pre-service evaluation time for pediatric patients with congenital defects includes additional time to discuss a patient's procedure with the parent. Similarly, the post-procedure work includes additional time to explain the pathology of the child to the parent. Furthermore, as a national standard, congenital heart programs are now also required to enter hemodynamic data and other procedural details into national registries such as Improving Pediatric and Adult Congenital Treatments (IMPACT), which can also add significant post procedure work time. In addition, the post-service period time typically includes time to diagram the congenital heart defect in the EHR and complete data submission to the registry.

(1) 93X3X

For CPT code 93X3X *Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections*, CMS disagrees with the RUC-recommended work RVU of 6.00 and proposes a work RVU of 5.50, based on a direct work RVU crosswalk to CPT code 32607 *Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral* (work RVU= 5.50, intra-service time= 45 minutes, total time of 178 minutes). Beyond

performing a basic search for other services with similar intra-service time, it is unclear what criteria CMS used to reject the RUC recommendation or to select this specific reference code as a direct work value crosswalk. CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital cardiac defects.

93X3X is typically somewhat more intense to perform than 93X2X, justifying a somewhat higher assigned physician work intensity. CMS proposed value would produce a rank order anomaly between 93X3X and 93X2X as the difference in intensities between these two services would not be appropriately reflected. For a normal connection patient, it will be straightforward. Risk of arterial catheterization is always high due to risks of stroke, bleeding into the brain for infants on heparin, femoral artery injury for infants. For an abnormal connection patient, the procedure is more complex, as doctors are now facing crossing arterial shunts or the PDA to evaluate the pulmonary arteries, or evaluating other vascular structures like MAPCAs, which can be multiple. Although the overall structures evaluated are still fewer than from a right heart catheterization (93X2X), when assessing the pulmonary arteries across shunts or a PDA, this is not typically well tolerated by the patient. These shunts are 3 or 3.5mm in diameter with a catheter being ~1.5mm, the procedure involves blocking roughly 50 percent or more of the entire blood flow to the lungs. These procedures require a significantly greater level of diagnostic evaluation, catheter and wire manipulation, and angiography to identify each and every vessel for surgical planning than previously afforded with the non-congenital diagnostic codes. Due to this, the physician work intensity is very high.

The RUC recommendation was based on the median work RVU from robust survey results and a favorable comparison to CPT code 93453 *Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed* (work RVU=5.99, intra-service time of 45 minutes, total time of 113 minutes) and CPT code 37248 *Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein* (work RVU= 6.00, intra-service time of 50 minutes, total time of 109 minutes). **The ACC urges CMS to finalize a work RVU of 6.00 for CPT code 93X3X.**

(2) 93X4X

For CPT code 93X4X Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections, CMS disagrees with the RUC-recommended work RVU of 7.91 and proposes a work RVU of 6.84, based on a direct work RVU crosswalk to CPT code 32608 *Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral* (work RVU= 6.84, intra-service time= 60, total time= 195). CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is

typically for pediatric patients with congenital defects. Furthermore, CMS' proposed value would assign 93X4X an intensity that is substantially lower than the top two key reference codes, even though 3/4ths of the survey respondents that selected those top reference codes indicated that the survey code was a more intense service than either reference code.

The RUC recommendation was based on the median work RVU from robust survey results and favorable comparison to CPT code 93461 Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization... (work RVU=7.85, intra-service time of 60 minutes, total time of 143 minutes) and CPT code 52356 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (e.g., Gibbons or double-J type) (work RVU= 8.00, intra-service time of 60 minutes, total time of 133 minutes). **The ACC recommends CMS accept a work RVU of 7.91 for CPT code 93X4X.**

(3) 93X5X

For CPT code 93X5X *Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections*, CMS disagrees with the RUC-recommended work RVU of 9.99 and proposes a work RVU of 8.88, based on the survey median work value. However, following detailed review of the physician work typically involved in this service, CMS determined that the survey respondents had underestimated the typical work involved. CMS' proposed value would assign this service a similar intensity to CPT code 93X4X, even though 93X5X is for a more complex patient with an abnormal native connection. CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital defects.

The RUC recommendation was based on the current work RVU for the code currently used to report this service (deleted code 93532) and favorable comparison to CPT code 92920 *Percutaneous transluminal coronary angioplasty; single major coronary artery or branch* (work RVU= 9.85, intra-service time of 68 minutes, total time of 127 minutes). **The ACC urges CMS to implement a work RVU of 9.99 for CPT code 93X5X.**

(4) 93X6X

For CPT add-on code 93X6X *Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects (List separately in addition to code for primary procedure)*, CMS disagrees with the RUC-recommended work RVU of 1.75 and proposes a work RVU of 1.44, based on a direct work RVU crosswalk to CPT code 37253 *Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for*

primary procedure) (work RVU= 1.44, intra-service time= 20 minutes, total time= 21 minutes). However, 37253 is a relatively less intense and less risky service typically performed in the lower extremity of an adult patient, making it an inappropriate crosswalk. The survey code is a more intense service typically performed on a more complex pediatric patient, where a Swan Ganz catheter is introduced from the venous sheath, advanced through the right heart, and placed into the pulmonary artery for purpose of assessing cardiac output by thermodilution. CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital defects.

The RUC recommendation was based on a direct work value crosswalk to CPT code 36483 *Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)* (work RVU= 1.75, intra-service time= 20 min) and favorable comparison to CPT code 20931 *Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)* (work RVU= 1.81, intra-service time of 20 minutes). **The ACC urges CMS to implement a work RVU of 1.75 for CPT code 93X6X.**

vi. Extended External ECG Monitoring Practice Expense

CMS seeks additional information to inform future rulemaking to set a national payment for the PE necessary to furnish these services (93241-93248). For these rhythm recording devices, the patient wears one small patch with two electrodes. The device is placed by the technician in the physician office and the patient is educated on the use of the device and the log diary. This would either be coded as 93242 or 93246, depending on the wear time. However, the patient does not return to the physician office to have the device removed. Rather, the device is returned directly to the device manufacturer who then scans it. The Independent Diagnostic Testing Facility (IDTF) has technicians who scan the data and create a preliminary report that is sent to the physician under code 93243 or 93247. The technician clinical staff work is not included in the professional component only code, CPT codes 93244 or 93248. The physician work captured in CPT code 93244 and 93248 includes the physician reviewing the preliminary report and interpreting a final report.

CPT code 93242 is performed by an electrodiagnostic technologist to obtain the recording and is typically provided in a physician's office and CPT code 93243 is performed by both an electrodiagnostic technologist and a cardiovascular technician to provide the scanning analysis with report and is typically performed in an IDTF. Although the new supply, ECG patch, is applied by clinical staff in the office, it is typically provided by the IDTF to the practice rather than purchased by the practice itself. For any rare rhythm clinics that report globally, the patch would be included in CPT code 93241.

Similarly, CPT code 93246 is performed by an electrodiagnostic technologist to obtain the recording and is typically provided in a physician's office and 93247 is performed by both an electrodiagnostic technologist and a cardiovascular technician to provide the scanning analysis with report and is typically performed in an IDTF. Although the new supply, ECG patch, is applied by clinical staff in the office, it is typically provided by the IDTF to the practice rather than purchased by the practice. For rhythm clinics that report globally, the patch would be included in CPT code 93245. The clinical staff work involved in applying the patch in 93246 includes the following: The patch is registered in the system and synced. Staff attach the device by applying adhesive patches after skin preparation that includes abrading the skin and cleaning of adhesive patch sites with alcohol pads and waiting for those areas to thoroughly dry. The device is activated and validated. After data analysis, the staff generates a report and completes a quality verification before report release.

Further detailed information about the code family, descriptions of clinical staff work for practice expense, and pricing of new supply code SD339 starts on page 1792 of the AMA/Specialty Society Relative Value Scale Update Committee's (RUC's) recommendations, available here. <https://www.ama-assn.org/system/files/2020-11/feb-2020-ruc-recommendations.pdf>.

The benefits of long-term continuous ECG monitoring are abundant, as shown in the selection of literature that follows. One study shows that long-term continuous monitoring results in higher, more accurate cardiac arrhythmia rates compared to short-duration cardiac recordings.⁵ Patients also benefit from this technology when faced with paroxysmal tachycardia, atrial fibrillation (AF) and flutter, other cardiac arrhythmias and abnormalities of the heart. To further elaborate on this point, another study shows that early identification of AF allows for the initiation of appropriate therapies to prevent the adverse health outcomes associated with AF.⁶ Additionally, when taking into account diagnostic capability and patient comfort, long term continuous ECG monitoring also demonstrated advantages. While Holter monitors have been the mainstay of clinical practice, they are challenging to wear, and P-wave signal quality is frequently inadequate. The P wave and PR segment are an integral part of an ECG and signal quality is of utmost importance for patient diagnosis. A study showed, a single-channel ambulatory patch ECG monitor, designed specifically to ensure that the P-wave component of the ECG be visible, resulted in a significantly improved rhythm diagnosis and avoided inaccurate diagnoses made by the standard 3-channel Holter monitor.⁷

⁵ Yenikomshian M, Jarvis J, Patton C, Yee C, Mortimer R, Birnbaum H, Topash M. Cardiac arrhythmia detection outcomes among patients monitored with the Zio patch system: a systematic literature review. *Curr Med Res Opin*. 2019 Oct;35(10):1659-1670. doi: 10.1080/03007995.2019.1610370. Epub 2019 May 28. PMID: 31045463.

⁶ Steinhubl SR, Waalen J, Edwards AM, Ariniello LM, Mehta RR, Ebner GS, Carter C, Baca-Motes K, Felicione E, Sarich T, Topol EJ. Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation: The mSToPS Randomized Clinical Trial. *JAMA*. 2018 Jul 10;320(2):146-155. doi: 10.1001/jama.2018.8102. PMID: 29998336; PMCID: PMC6583518.

⁷ Smith WM, Riddell F, Madon M, Gleva MJ. Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours. *Am Heart J*. 2017 Mar;185:67-73. doi: 10.1016/j.ahj.2016.11.006. Epub 2016 Nov 26. PMID: 28267477.

Given the differences provided in the detailed paragraphs above, the ACC urges CMS to reconsider the reimbursement rates set for long term continuous ECG monitoring. Due to the fact that the scanning analysis codes (93243 and 93247) are currently reported by IDTFs directly to Medicare and the patch is provided and not purchased by the physician practice for the recording codes (93242 and 93246), the ACC is unable to provide traditional reimbursement recommendations for the extended external ECG patch, medical magnetic tape recorder. This supply was listed as SD339 with a price of \$413.24 in 2021 proposed rulemaking before CMS opted to utilize contractor pricing for the scanning and analysis code. However, the societies shared a reasonable proxy for the various patch technologies that are typically used for 7-day and 15-day services with the RUC and subsequently CMS, when these codes were originally presented. In addition, CMS and its contractors have been paying for these services under Category III codes 0297T since 2013. The Agency should have the necessary information to parse out appropriate average pricing for the patch used in both the 7-day and the 15-day service based on contractor pricing. Finally, the ACC has continued to encourage IDTFs and other stakeholders with access to relevant information to share additional feedback and documents with the Agency so national rate setting can occur.

vii. Embolic Protection

The ACC appreciates CMS' proposed work RVU of 2.50 for new CPT code 33XXX for transcatheter placement and subsequent removal of cerebral embolic protection devices. This work RVU is the same as the RUC recommendation.

II. Other Provisions

A. Proposal to Establish Values for Remote Retinal Imaging (CPT code 92229), Comment Solicitation for Fractional Flow Reserve Derived from Computed Tomography (CPT code 0503T), and Comment Solicitation for Codes involving Innovative Technology

As CMS states, current practice expense (PE) methodology may not account for innovative technologies such as those that utilize software algorithms and artificial intelligence (AI) can augment and/or substitute physician work. There are several limitations which hinder accurate valuations of technologies which utilize software algorithms and AI to assist or substitute physician work. These technologies are still in their infancy and are not widely utilized yet across all medical specialties. There are only a few devices and procedures in the cardiovascular space utilizing software algorithms and AI, making it difficult to properly value. Additionally, devices using these technologies are often developed by a single manufacturer, making it incredibly difficult to get accurate pricing data due to confidentiality and trade secret limitations evoked by the manufacturers. Finally, as CMS accurately states, current methodologies may not accurately capture indirect costs associated with the procurement of these new technologies.

As more products and procedures utilize software and/or AI to augment or substitute for physician work, it is vital that CMS work closely with the AMA CPT and RVS Update Committee (RUC), medical specialty societies such as the ACC, patients, and medical device manufacturers to develop a more accurate process for valuing innovative technologies that may improve quality of care without unnecessarily devaluing services and limiting access to care. There are also inherent limitations to current reimbursement structures that are hard to solve. To address these limitations, CMS should continue to develop alternative payment models which incentivize the use of new, innovative technologies to provide high quality care and transition away from traditional fee for service models of reimbursement and care. Finally, any solutions to address inaccurate valuations should ensure that patients are not denied access to quality care, do not exacerbate inequities in the health care system, and should promote diversity and inclusion efforts to ensure historically marginalized populations and communities are afforded equal access to these technologies. As these technologies come to market in the coming years, the ACC looks forward to continuing to work with CMS, the AMA, and other stakeholders to ensure accurate valuation and reimbursement for this growing class of technologies without stifling innovation.

As a practical matter, it remains the case that the cost of 0503T *Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model* for a physician office and the facility setting is the fee charged by the vendor. Invoices shared by ACC members demonstrate this cost to be \$1,100. The ACC appreciates CMS' effort to set a national rate for this Category III CPT service, but disagrees with the proposal to use hospital outpatient cost reporting data to identify a target that can be approximated through a practice expense crosswalk. In prior outpatient comments, the ACC has expressed concerns that facility cost reporting mechanisms fail to fully capture the cost of this service. Cost reporting has improved with time and outpatient costs for 0503T have trended higher, but for systemic and procedural reasons, remain below the price of \$1,100 on an invoice. **The ACC urges CMS to update its proposal to include a price of \$1,100 as a direct expense input for 0503T.** The ACC will separately provide a confidential/deidentified invoice as an example of this pricing.

Finally, the ACC cautions CMS against viewing innovative software technology as something that may only augment and/or substitute physician work while only decreasing or increasing complexity. Each of those shifts is possible with any software technology and even with its use on any individual patient. Under the current fee schedule and resource-based methodology, these impacts will have to be managed on a service-by-service basis. In the case of FFRCT, additional analysis of an already obtained and interpreted imaging study is further analyzed for patients with intermediate coronary disease to further guide care decisions. That represents an additive element in a patients care that can improve outcomes, as some patients who may have otherwise undergone procedural interventions are shifted to more conservative treatment or vice-versa based on the additional information provided.

B. Medicare Shared Savings Program (MSSP)

i. CMS Web Interface Reporting

The ACC strongly supports CMS’ proposal to allow MSSP quality reporting via the CMS Web Interface through 2023. Many MSSP participants began preparations for reporting through a different mechanism when elimination of the Web Interface was first proposed. Even now, sites are still updating their systems and reviewing the accuracy of EHR data collection to prepare for the sunset of the Web Interface. This additional time will allow participants and ensure accurate data collection and data validity before reporting through a new mechanism is used for scoring.

ii. Role of Specialists in ACOs

A recent study published in *JAMA Health Forum* concluded that simultaneous participation in both an ACO model and bundled payment program resulted in lower post-acute spending and readmissions than participants in bundled payments alone.⁸ This finding may illustrate how care design efforts occurring at both the population/ACO level and targeted specialty/bundle level could drive value.

Specialists in ACOs should be an established member of a patient’s ongoing care team beyond acute events. Under the ACO model, early and ongoing care coordination between the primary care and cardiology teams should be encouraged in the early work-up and diagnosis of a patient with a cardiovascular condition. This allows both the primary care and specialty teams to identify key interventions for the patient and to establish a care plan aimed at preventing further disease progression.

iii. Quality Reporting for Specialists under the APM Performance Pathway (APP)

While many cardiologists are now in ACOs under the expansion of the MSSP, it remains challenging for specialists to fully engage in the model under the current quality reporting structure. Measures in the ACO measure set focused on statin therapy, controlling high blood pressure, and tobacco cessation reflect actions that are important in the prevention or management of cardiovascular disease; however, many of these actions may occur as part of primary care services and may not engage cardiology. The ACC agrees that the future inclusion of specialty-specific measures in the APP measure set could increase specialty engagement in ACOs. Having specialty-level performance data can help drive conversations focused on improving the quality of care across all clinicians in the ACO.

⁸ Navathe AS, Liao JM, Wang E, et al. Association of Patient Outcomes With Bundled Payments Among Hospitalized Patients Attributed to Accountable Care Organizations. *JAMA Health Forum*. 2021;2(8):e212131. doi:10.1001/jamahealthforum.2021.2131

However, the addition of specialty-level measures alone may not be effective unless CMS determines how to better align incentives between primary care and specialists under the ACO. Some ACO entities may be hesitant to incorporate additional specialty measures due to the additional reporting burden this may create. Entities may also consider how many patients are attributed to their specialists under the ACO before determining whether to report specialty-level measures. CMS should review the current ACO scoring structure to ensure that entities find value in reporting quality at the specialty level.

If specialty-level measure sets are not incorporated as part of the quality measures that are reported to CMS, the Agency should consider how to encourage ACO entities to maintain specialty-specific quality measurement internally. These data can drive conversations about quality and ensure that clinician incentives are available to all clinician team members under the ACO, whether primary care or specialty focused.

C. Appropriate Use Criteria (AUC)

CMS indicates that the earliest claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. This is because it would not be possible to finalize implementation and claims processing plans in this final rule (typically published on or before November 1) and make those decisions effective any earlier than the 3rd calendar quarter of 2022. Therefore, CMS believes the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023. Therefore, CMS proposes to begin the AUC claims processing systems edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID-19 ends.

The ACC agrees that preparation for the AUC Program has been significantly disrupted for both CMS and practices. The College supports this proposal to defer claims processing system edits and the penalty phase of the program as proposed, and looks forward to continued collaboration with the Agency to strive for a smooth rollout of the program.

D. Removal of Selected National Coverage Determinations

In a process shift, CMS has begun using the fee schedule rulemaking process to remove outdated NCDs rather than the NCD process. The ACC does not believe one mechanism is superior over the other, 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. PET scans for non-oncologic indications and agrees with CMS that removal of the NCD and deferring coverage to local MACs would better serve the needs of the Medicare population. **The ACC supports CMS' proposal to remove NCD 220.6.** The ACC is hopeful that deferring coverage decisions to local MACs will not impact affirmative coverage moving forward and patients will continue to have access to this imaging service. The ACC is also in

agreement that as new non-oncologic PET agents are being approved by the FDA and the appropriate use of these agents being supported through published guidelines, local coverage decisions would be the fastest path to access for appropriate candidates.

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.

E. Physician Self-Referral Updates

The ACC remains concerned that the complexity of the Physician Self-Referral Law regulations (“Stark Law”) continues to pose barriers to the move to value-driven team-based care despite the most recent revisions finalized at the end of 2020. In this proposed rule, CMS proposes to codify revisions that further narrow the definition of an indirect compensation arrangement at § 411.354(c)(2)(ii)(A)(2) and (3) to recognize the following:

“... that the referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services and the individual unit of compensation received by the physician (or immediate family member): (1) Is not fair market value for items or services actually provided; (2) Is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation that positively correlates with the number or value of the physician's referrals to the entity; (3) Is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation per unit that positively correlates with the physician's generation of other business for the entity; or **(4) Is payment for anything other than services personally performed by the physician (or immediate family member).**”⁹

CMS further states that services personally performed by the physician (or immediate family member) would *not* include services performed under the supervision of the physician, including employees, independent contractors, and group practice members. To provide patients with higher-value care, many cardiologists have developed cardiovascular care teams comprised of advanced practice professionals who may be part of the group practice as employees or contractors. Based on our interpretation of the proposal, a financial relationship involving care provided by advanced practice professionals under the supervision of a physician would not meet the definition of an indirect compensation arrangement eligible for a Stark exception.

⁹ 86 Fed. Reg. 39323 (July 23, 2021).

The codification of the fourth condition above may create further confusion around the definition of an indirect compensation arrangement that may qualify for a Stark exception. The College is especially concerned that this may lead to the need for additional legal interpretation and compliance hurdles as groups work to integrate more advanced practice professionals into their care team. **The ACC recommends that CMS reconsider limiting the “indirect compensation arrangement” definition to only include services personally performed by the physician (or immediate family member) as written in the proposed § 411.354(c)(2)(ii)(A)(4). CMS should ensure these proposed changes and future revisions to the Stark Law truly enhance the move to value-based care and do not interfere with cardiologists’ ability to form effective care teams .**

III. Requests for Information

A. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs

CMS states its intent to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. Over the last few years, CMS, along with efforts led by the Office of the National Coordinator for Health Information Technology (ONC), have developed policies meant to move the American health care system closer towards true semantic interoperability. **The College applauds the innovation direction HHS, CMS, ONC, and other regulatory agencies are taking to help develop a health system that allows for data liquidity and digital quality measurement through standardization and interoperability efforts.** As CMS correctly notes, multiple standards being used to report electronic clinical quality measures (eCQMs) is challenging and burdensome. Organizations have been reporting with eCQMs for over a decade, are acutely aware of the shortcomings of siloed data collection, and understand the potential benefits standardized dQMs across reporting programs could have on reporting burdens and interoperability.

However, the transition to a fully digital quality measurement system will take time and considerable resources. The College encourages CMS continue the development of policies that shift health care to a fully interoperable, digitally connected care delivery system. CMS needs to implement these changes in a stepwise manner with thoughtful timelines that do not place unrealistic implementation requirements and costs on health care clinicians, health systems, and health information exchanges (HIEs) or registries, quality measure developers, and other sources of digital health information. **While encouraged by CMS’ urgency to work on issues surrounding digital quality measurement and interoperability, a move to full digital quality measurement by 2025 threatens to place undue burdens and costs on the system, unfairly punish rural and underserved health care settings that lack the necessary infrastructure and funding, and risks exacerbating digital and health inequities that exist in health care today.** Instead, the ACC recommends CMS work side by side with stakeholders to develop a phased implementation timeline while providing sufficient technical assistance and resources to allow for the necessary work to move to a fully digital quality measurement system.

i. ACC Efforts to Create Standardized Quality Measures

Health Level Seven International® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) standards have evolved and provider burden increased through data collection processes. The College has partnered with the Chesapeake Regional Information System for our Patients (CRISP) to build upon known standards and systems to allow healthcare organizations which partner with the National Cardiovascular Data Registry (NCDR®) and other registries to accelerate the adoption of modern data standards and reduce provider reporting burdens. This effort is a multiyear project intended to develop a solution and an implementation guide for sites contributing to NCDR® and other registry data collection, leverage the Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR application programming interfaces (APIs), and work with health systems and their vendors to develop a pilot solution that will extract data according to the FHIR standard. Experience gained through this pilot project will allow NCDR®, CRISP, and other entities to gain experience and help advance standards that can be implemented at scale to improve efficiency of data collection effort.

The project currently focuses only on the CathPCI Registry®, one of nine hospital and ambulatory care setting registries operated by the ACC. **However, a complete cross walking of all quality measures contained in the NCDR® registry suite by 2025 will take time and resources the ACC currently does not have.** Clinical data registries, such as NCDR®, are an essential component of quality measurement and data collection in the American health care system and are relied upon by patients, clinicians, institutions, medical device manufacturers, and regulatory agencies to inform clinical, cost, coverage, and quality decision making. **As CMS embarks on the process to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, it is imperative CMS provide sufficient time, resources, and technical assistance to quality measurement developers such as the ACC and data sources such as the NCDR® to help with the transition.** The transition must be gradual and stable; it is difficult for organizations, particularly medical societies, to dedicate the necessary resources to an effort if the Agency's expectations change year after year. Failing to provide this clear direction only places financial and administrative burdens that will prevent CMS from reaching its intended goal of fully transitioning to digital quality measurement across reporting programs and care settings.

ii. Definition of Digital Quality Measures

CMS proposes defining digital quality measures as “as quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. A dQM includes a calculation that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources.”

The ACC appreciates CMS attempting to refine the definition of digital quality measures from the previous definition of “sources of health information that are captured and can be transmitted electronically and via interoperable systems.” **However, the newly proposed definition is still too broad to be meaningful.** For example, if a physician manually enters a patient’s blood pressure into the appropriate field of the EHR throughout the year, manually abstracts that information and sends it as a quality measure through a digital transfer, it will meet the proposed definition. Likewise, a physician could create an interface whereby blood pressure readings are obtained at home, seamlessly and securely flow into the appropriate field of the EHR through digital transfer, are abstracted and sent as a quality measure. The first example involves analog to digital transfers while the latter is a digital-to-digital measurement system that aligns much more closely to CMS’ vision for digital quality measurement, yet both would fit the definition proposed. The proposed definition also encompasses non-traditional data sources such as wearable devices which may fall outside of CMS and other regulatory agencies’ purview. While industry partners developing these devices are actively working to create and adhere to standards, a lack of required data standards, such as adherence to FHIR, could complicate data collection processes and threaten to slow down or prevent data exchange. The overall intent and infrastructure of this definition for dQMs should consider potential reliability and validity issues for new or existing measures. **Due to this, the ACC recommends CMS revisit the proposed definition and more specifically align the definition with the requirements quality reporting and value-based purchasing programs would need to meet to fulfill regulatory requirements as well as more clearly defining what differentiates digital quality measurement from existing measures and methodologies.**

iii. Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to Digital Quality Measures by 2025

CMS states its intent to further modernize the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector where appropriate. **The ACC appreciates CMS’ intent to continue to build on the interoperability provisions in the 21st Century Cures Act and work towards the development and deployment of a truly interoperable health care system.** The advancement of a standards-based approach with well developed, mature use cases and alignment across reporting programs and care settings will help patients and clinicians ensure data is accessible and can be accurately and appropriately captured and measured for quality and care coordination purposes.

iv. Leverage and Advance Standards for Digital Data and Obtain all EHR Data Required for Quality Measures via Provider FHIR-based APIs

While the ACC agrees that computational advancements and further development of artificial intelligence, machine and deep learning, deployment of natural language processing, and

utilization of big data analytics can help increase the utility of data captured across care settings from diverse sources, the College cautions CMS from assuming institutions and providers have equal access to such tools or they may be the panacea for all interoperability and quality measurement shortcomings. **Proper development of digital quality measures will take considerable time, resources, and expertise to deploy.** Not all sources of digital health measurement may adhere to federally required standards and fall outside the scope of regulation, such as certain patient generated health data, social determinants of health, and other emerging methods of health data collection. These non-standardized sources of data will require additional work to allow for use for quality measurement purposes. Finally, once interoperable, standardized data collection systems are fully developed and deployed, advancements in these standards, necessary updates and system upgrades require considerable maintenance from IT departments to ensure APIs continue to function safely and effectively. It is essential that CMS remember the amount of time necessary to prepare for, deploy, and maintain required health IT systems and ensure implementation timelines account for the reality on the ground.

v. Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

The ACC supports CMS' intent to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector where appropriate. The move to aligned, digital quality measurement will allow for real-time quality and cost measurement at a more granular level. This, in turn, will better prepare clinicians and organizations for participation in value-based payment models and provide patients with more useful insights about their care. As CMS aligns reporting programs, CMS needs to understand and consider the significant time and resources clinicians, organizations, specialty societies, registries and others pour into preparation and participation in these reporting programs through the development and deployment of quality measurement tools. Program stability and measured deployment will be essential to creating an environment where aligned reporting programs succeed.

B. Closing the Health Equity Gap in CMS Clinician Quality Programs

Like CMS, the ACC is committed to advancing equity in the delivery of healthcare and healthcare quality to reduce disparities in cardiovascular practice. The College appreciates the administration's focus on health equity and CMS' action to evaluate and implement initiatives in reducing disparities, including this RFI for reducing gaps in care. The enormous costs of U.S. healthcare spending on cardiovascular disease and cardiovascular risk warrant further examination of factors outside of patient care that may contribute to disease. The American Heart Association's most recent "Heart Disease and Stroke Statistics - 2021 Update" used data from MEPS (the Medical Expenditure Panel Survey) to illustrate that the annual direct and indirect costs of cardiovascular disease in the United States for 2016-2017 was an estimated

\$363.4 billion.¹⁰ Overall, a study by the W.K. Kellogg Foundation and Altarum states that disparities account for roughly \$93 billion in excess medical care costs and \$42 billion in productivity lost per year.¹¹ It is clear that improved data collection and quality measurement will be instrumental in helping inform and develop policies to curb costs and potentially reimburse higher quality care, especially given anticipated increases due to an aging population and growth.

i. Data Collection on Social Determinants of Health (SDOH)

The ACC supports CMS' efforts to improve the standardization and collection of SDOH to improve our understanding of additional factors that may influence health outcomes. Resources such as the NQF MAP Health Equity Advisory Group and Best Practices for Testing Risk Adjustment Models white paper may be useful in determining the appropriate socioeconomic risk factors and highlight considerations such as standardization, resource availability, and implementation issues. We applaud CMS' efforts to date in working with experts from external organizations in the development and use of health equity data and algorithms.

The College believes that data collection efforts should go beyond examining race and ethnicity and include a host of other risk factors to better inform clinicians of patient outcomes. The "Heart Disease and Stroke Statistics - 2021 Update" provides a variety of examples of SDOH which impact cardiovascular disease. Other factors for consideration include access to healthy food, structured racism, income, occupation and work condition, education level, physical and leisure activity, gender, cultural beliefs, language, number of social contacts, family support, neighborhood social cohesion, air pollution, number of household members, sleep quality, health insurance status, and access or distance to appropriate medical care (such as in the case of door to balloon times). We also believe that poverty plays a significant role in evaluating quality and outcomes, which can be measured via zip+4 code. While these additional elements may be beyond the scope of the proposed RFI, it is also important to factor in data about the pathophysiology and natural history of a disease or condition, genetic and hormonal influences, disease or condition symptoms, general stressors (which is critical in their impact on CV disease) optimal diagnostic testing, and benefits and risks of therapeutic interventions.

As CMS examines race, ethnicity, and other disparities at the practice level, it may also be helpful to also identify those aspects of practice that are under a clinician's control but not influenced by SDOH, such as procedural complications. The ACC welcomes the opportunity to explore this topic and all efforts related to improving SDOH data collection with CMS.

ii. Limitations of Data Collection

¹⁰ Virani SS, Alonso A, Aparicio HJ, et al. Heart Disease and Stroke Statistics-2021 Update: A Report From the American Heart Association. *Circulation*. 2021;143(8):e254-e743. doi:10.1161/CIR.0000000000000950

¹¹ The Business Case for Racial Equity: A Strategy for Growth. Altarum. Published October 26, 2018. Accessed September 9, 2021. <https://altarum.org/RacialEquity2018>

The ACC recognizes that health equity-focused data collection alone will be a significant effort and appreciates CMS' commitment to this topic. While the College encourages CMS to continue this effort, we share some of our observations below regarding potential limitations and risks.

First, the ACC expresses caution in using an indirect estimation method for race and ethnicity for readmission or individual-level directed measures. Indirect estimation allows for use of other readily available information in estimating missing variables of interest, which in this case are race and ethnicity. This is understandably a short-term solution, but as proposed by CMS, we suggest caution before full implementation or at least a trial period since the data may not be accurate and therefore unusable. Relevant sociodemographic factors should be utilized in an analysis unless there are conceptual reasons or empirical evidence indicating that adjustment is not appropriate or necessary. Analysis should also consider unintended consequences of stratification for the patient population, providers, health plans and systems if measures are used in accountability programs such as pay-for-performance or public reporting. The ACC agrees that data stratification may help identify patient populations and targeted quality improvement strategies for those most vulnerable to health inequities; however, we also agree with CMS about the unintended consequences that may result if data are inaccurate.

Second, the CMS references self-reported sociodemographic data as the gold standard; however, many clinicians already find it difficult to collect this information from their patients. Clinicians and administrative leadership must be aligned in the commitment to collect or manage disparity initiatives; as with all quality initiatives, these must not be burdensome with either costs or time. Additionally, a lack of data standardization in SDOH measures hinders collection efforts and prevents necessary data liquidity. Integrated health systems might have a better ability to enact change or to collect data, whereas smaller practices might have fewer resources to do this. **In addition, CMS should also consider how clinical registries such as the NCDR®, could serve as partners in collecting this type of data. The ACC believes CMS should ensure efforts to develop and collect SDOH data should align with other federal initiatives through improved standardization.** This will improve semantic interoperability and allow for more nuanced and useful applications of SDOH data.

Third, it is important to keep the patient in mind as part of any expanded data collection effort. Many patients may have questions as to how data related to their sociodemographic background is important to their care. Ensuring that beneficiaries feel comfortable sharing this information with clinical and administrative staff should be the top consideration of any health equity initiative.

iii. Future Efforts to Reduce Health Disparities

The ACC appreciates CMS' work to address the longstanding healthcare disparities that have come to light during the COVID-19 pandemic. The College agrees that there is value in developing new measures as well as refining existing measures and programs to address health equity. Tying these measures to value-based models such as MSSP and the QPP can certainly incentivize improvements in the care of underserved populations; however, the College

encourages CMS to proceed cautiously in order to ensure that any health equity focused incentives truly serve the patient population.

As part of this effort, CMS should also identify solutions to common barriers in care. For example, the ACC has long advocated for access to regular cardiac rehabilitation services following an acute cardiac event or procedure. However, many beneficiaries report being unable to complete a full course of rehabilitation due to the \$20 copay per visit or challenges with transportation to a facility. CMS should determine how to ensure beneficiary access to services such as cardiac rehabilitation, which have the ability to improve patient outcomes in the long-term.

Finally, the ACC recognizes that achieving health equity will require collaboration across stakeholders outside of the medical community and CMS. Community organizations and local entities will be crucial to addressing needs related to food, housing, employment, and other socioeconomic support that have an impact on beneficiary health and access to care. While impacting some of these factors will be a challenge for clinicians, the ACC remains committed to working with CMS to determine how to engage the broader beneficiary and stakeholder community to holistically address disparities in care.

C. Additional Objectives Adopting FHIR®-based API Standards

CMS seeks to align additional PI performance category objectives with approaches utilizing HL7® FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. The College supports efforts for CMS to work with ONC to align measures and objectives from the PI and other categories under MIPS and MVPs to best support improved interoperability. The widespread deployment of standards-based API functionality is a step in the right direction and any incentive CMS can provide eligible clinicians and institutions to implement these standards will help drive utilization. As CMS seeks to align additional objectives, it is imperative that these objectives align with implementation timelines for technical requirements set forth in the 21st Century Cures Act final rules. **CMS should not require the adoption of technical requirements for any reporting year before they are required under the previously finalized rules.** The ACC encourages CMS to work closely with ONC to align implementation timelines and ensure any objective specifications match requirement timeline set forth in other rules.

D. Request for Information on Patient Access Outcomes Measures

CMS requests information from stakeholders on several matters related to patient access outcome measures. One question on which CMS seeks input is whether to require providers to maintain a record of third-party applications which patients have used to access their patient health information through APIs incorporated within certified technology so that this information could be used to assess patient usage of these applications. **While the College appreciates CMS' intent to assess patient usage of third-party applications and how they may be used,**

any requirement for providers to track patient third party usage would be incredibly burdensome on providers and nearly impossible to execute. Clinicians and patients should work together to understand how third parties use electronic health information and ensure it is safeguarded as the third-party application health ecosystem develops in response to the 21st Century Cures Act Information Blocking and Interoperability rules. However, it is not the role of a clinician to supervise and track patient activity. Documentation requirements for such a measure would also only contribute to a growing list of clinician burdens that are leading to burnout, a threat CMS has stated needs to be reversed. The College recommends CMS evaluate other methods, including working with trusted third parties such as those in the BlueButton 2.0 program, to better understand patient usage and collect valuable insights to help promote safe usage.

E. Request for Information on Clinical Notes

In comments previously submitted to ONC and CMS, the ACC has stated unequivocally that patients own their health information and should have access to it when they want, how they want. This includes information contained in clinical notes. The ACC is supportive of efforts from both CMS and ONC to further interoperability and free patient data, allowing them to access, store, and utilize their health information any way they see fit. **While furthering this goal though, CMS should not duplicate requirements that could be instituted through the 21st Century Cures Act regulations and add to administrative burdens for eligible clinicians through additional reporting measures and objectives.** While supportive of incentives to improve interoperability and further the Open Notes movement, CMS has made strides in reducing reporting burdens through the Meaningful Measures Initiative. The ACC asks CMS and ONC to continue to work together to align incentives while working to reduce reporting burdens instead of adding measures and objectives that may be duplicative to other regulatory requirements.

IV. Quality Payment Program (QPP) & Merit-Based Incentive Payment System (MIPS)

A. MIPS Value Pathways (MVP)

The ACC appreciates CMS' efforts to alleviate the administrative burden of MIPS, streamline quality reporting, and support clinicians in the to move to Alternative Payment Models (APMs). While the College agrees that the MVP and subgroup reporting proposals offer the opportunity for cardiologists to focus on more clinically meaningful measures under MIPS, we urge CMS to proceed cautiously with these proposals to ensure that they do not inadvertently create additional confusion and complexity for participating clinicians and groups.

i. MVP Timeline and Transition from Traditional MIPS to MVPs

The ACC thanks CMS for the additional development criteria and guidance provided in the rule concerning MVPs and agrees with the delay of MVP implementation until at least

2023. Due to the current COVID-19 pandemic and continued concerns around the impact of patient care, the College believes clinicians and the medical community will require additional support and resources to prepare for continued changes to the Quality Payment Program and MVPs. 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 agrees with the proposed phased approach in the implementation of MVPs. **In addition, the ACC agrees with the proposal that MVP participation should remain voluntary and self-assigned, providing clinicians the flexibility to participate at their discretion over the trajectory of the program. CMS should not automatically assign clinicians to MVPs.**

CMS proposes to sunset the MIPS program as currently structured (“traditional MIPS”) at the end of the CY 2027 performance period and make MVP reporting mandatory by CY 2028. **The ACC recommends that CMS not finalize this timeline at this time and instead continue to revisit this in future rulemaking.**

ii. Supporting Clinicians Through the Transition to MVPs

While the College recognizes that this transition aligns with the move to APMs, CMS must ensure that participants are prepared. Although the MVP concept was introduced in CY 2021 rulemaking and further explained in this proposed rule, clinicians are still trying to understand how MVPs function at a practical level. CMS should provide education to participants over the next few years through town halls meetings, information sessions, fact sheets, technical assistance, and partnerships with specialty societies, similar to what was provided during initial MIPS/QPP implementation.

iii. Clinician Support for Population Health Claims-Based Measures

To ensure that the MVPs serve as the intended glide path to APM participation, CMS must consider ways to provide clinicians with the ability to understand their performance on all measures, particularly the foundation-level hospital admissions measures (*Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (NQF #3495)*), the *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (NQF #3597)*), and cost measures.

Although the College has continued concerns related to the specific measures, which will be discussed later in this letter, we recognize that many APMs currently utilize these or similar measures for cost and quality performance. **Therefore, in order to ensure that MVPs truly serve as a glide path to APM performance, the ACC strongly recommends that CMS support clinicians with the data necessary to understand performance on these measures.**

In addition, the ACC recommends implementation of a “hold harmless” informational period in which CMS provides participants with their benchmark performance. These

reports should include drill-down data to each clinician within a practice, similar to the data provided by the Quality and Resource Use Reports (QRURs) under the Value-Based Modifier Program and the field test reports distributed in the early stages of QPP cost measure development.

Having these datasets would allow clinicians to identify potential errors in the collected claims data, such as clinicians who may be mistakenly assigned to a practice. In addition, the datasets would allow clinicians to see which services are attributed to their practice and determine where there are opportunities to improve care coordination with other clinicians. Access to this data and the ability to understand it and act on it in a timely manner continues to be a core element of successful APM participation. **The ACC reiterates the importance of establishing scoring and data sharing practices that support clinicians in becoming familiar with these claims-based foundation and cost measures if they are implemented in the MVPs.**

iv. MVP Development

To fully transition from traditional MIPS, CMS must also ensure that there are sufficient MVPs available to meet the intended goal of providing all clinicians with more meaningful measure sets. The ACC is concerned that in the absence of meaningful MVPs, some groups may be forced to default to a measure set that is not reflective of their practice and patient population. CMS should continue efforts to work with clinicians and specialty societies on the design of new clinician-led MVPs. Measures should be based on claims and focus on outcomes in order to reduce burden and allow for clinicians to focus on patient care. The ACC urges CMS to consider how to best construct MVPs for specialties such as cardiology which are inclusive of several subspecialties. It is still unclear as to whether a single MVP for cardiology that encompasses all cardiovascular care would be most beneficial to clinicians and patients, or if creating discrete MVPs by subspecialty/patient population is more beneficial.

The ACC recommends that relevant stakeholders, including practicing clinicians and specialty societies, have the opportunity to provide input into the development of potential MVPs before they appear in the NPRM. Public announcements through CMS could be posted to ensure that all relevant groups are provided a platform to influence the development of MVPs that may in the future affect their practice. The ACC believes that increased collaboration and transparency between CMS and the specialties is necessary to develop MVPs that capture the appropriate intent of a clinical scenario. While third parties may have an interest in developing an MVP, we believe that development should be clinician-led and represent the input of all members involved in the care team for that particular condition.

As CMS seeks input on MVPs, it would be helpful to understand the full list of clinical areas that CMS may be considering. For example, several measures in the Chronic Disease Management MVP may also apply to cardiologists. Understanding CMS' thoughts around this MVP and others that may involve cardiovascular care, would provide groups such as the ACC with a better sense of which clinicians and patient populations may be captured in each MVP category.

The ACC also recommends that CMS provide timely access to data on quality, cost and population health measures, which are key to identifying opportunities for MVP development. When recommending measures for the MVPs, it is helpful to know how many clinicians/groups are currently reporting a measure, the specialty breakdown of reporting, and whether a measure is approaching topped out status or if there is still room for improvement. Having this information allows the ACC to identify measures that are both clinically relevant, but also likely to be reported by participants so that CMS reaches its necessary sample thresholds.

The ACC agrees with the proposal for an annual maintenance process for MVPs as this will ensure that the MVPs maintain relevance for current practice and standards. However, the College requests that CMS consider how to align this process with other annual reviews such as the Measures Under Consideration (MUC) and QCDR self-nomination to minimize the burden on stakeholders.

v. Future Vision of Subgroups - Vision for Data Granularity

CMS envisions an end state where technology will allow for the submission of discrete data elements and allow us to calculate measure performance for clinicians, subgroups, groups, and APM Entities, rather than having measure performance aggregated and calculated at a group or subgroup level prior to reporting. **This vision aligns not only with the vision put forth by Congress under the 21st Century Cures Act and the Office of the National Coordinator for Health IT (ONC), but also the ACC and its leadership.** The College is currently undergoing a digital transformation by investing time, money, and resources to help provide members of the CV team with the technological tools and knowhow to best serve patients and operate in a health care system with true interoperability and data granularity. **The ACC thanks CMS and other regulatory agencies for working to bring this vision to life and stands ready to engage with any and all stakeholders to ensure this vision comes true.**

vi. Comments on Proposed MVPs

(1) Heart Disease MVP

The ACC appreciates CMS' consideration of our prior feedback on the proposed Heart Disease MVP. We recognize that measure gaps remain; however, due to the complexity of this patient population, continued refinements to this pathway will be needed.

ACC's recognizes that this pathway includes measures related to heart failure, ischemic heart disease, and several broadly applicable measures relevant to heart disease. However, some pertinent measures that would be applicable to a Heart Disease MVP are not included, such as those related to rhythm disorders, complications, and pharmacotherapy (e.g., anticoagulation for atrial fibrillation). Overall, we believe that the MVP falls short of capturing heart disease as a condition, and in general is not inclusive for all of heart disease/cardiology or a broad-based

heart program. The ACC offers to work with CMS to further refine this pathway between rulemaking cycles.

As with many other MVPs, we recognize that gaps remain in incorporating the patient voice, such as through the use of patient-reported outcome measures. While we are not suggesting their use in this MVP, surveys such as the Kansas Living with Heart Failure Questionnaire and the Seattle Angina Questionnaire may prove useful if implemented at a future date.

ACC's comments on specific measures under the four performance categories for the Heart Disease MVP are below.

a. Quality Measures

Heart Disease MVP Proposed Quality Measures			
Quality Measure	NQF #	CMS #	ACC Comments
HF: ACE inhibitors or ARB or ARNI Therapy for LVSD	0081*	005	<i>No comments</i>
CAD: Beta Blocker therapy - prior MI or LVEF<40%	0070*	007	<p>There are several concerns with this measure:</p> <p>In regard to “CAD: Beta Blocker therapy – prior MI,” beta-blocker therapy is not indicated indefinitely following most myocardial infarctions. The studies that demonstrated mortality benefit following myocardial infarction were performed prior to current medical reperfusion therapy with acute percutaneous coronary intervention or thrombolytics as well as aspirin and statins. Modern therapy has led to a substantial decrease in size of myocardial infarction. As outlined in the ACC publication, “How Long Should We Continue Beta-Blockers After MI?,”¹² the scientific rationale for beta blockers in the many patients post-MI whose left ventricular ejection fraction remains normal is limited, given the limitation of MI size now seen with reperfusion, aspirin and statin therapy. By avoiding substantial myocardial necrosis and scar formation with contemporary management, the benefit of beta-blockers in preventing sudden cardiac death via scar-based reentrant arrhythmias is attenuated.</p> <p>During the early trials performed prior to reperfusion therapy that did show a beta-blocker benefit, myocardial infarctions were determined by measuring</p>

¹² How Long Should We Continue Beta-Blockers After MI? American College of Cardiology. Accessed September 9, 2021. <https://www.acc.org/latest-in-cardiology/articles/2017/01/20/09/36/http%3a%2f%2fwww.acc.org%2flatest-in-cardiology%2farticles%2f2017%2f01%2f20%2f09%2f36%2fhow-long-should-we-continue-beta-blockers-after-mi>

			<p>the release of intracellular creatine phosphokinase (CPK) from necrosing myocardial cells. MI's are now diagnosed by measurement of another enzyme released from necrosis of myocardial cells, troponin. Troponin is more specific to the heart than CPK and assays have been developed over the last 20 years to measure minute increases of troponin in the blood. Thus, tiny MI's can be diagnosed by minute increases in troponin. As such, patients with chest pain symptoms that would have been diagnosed as unstable angina based on the CPK levels being within the limits of normal in the past are now found to have small MI's based on the small increase in troponin levels. Beta blockers have not been studied in patients with these very small MI's to determine if they are beneficial.</p> <p>Meta-analyses of all comers of patients with MI's being treated with contemporary management have not shown a mortality benefit of beta-blockers, but have shown a small decrease in recurrent MI and angina. These benefits attenuate with time, however, and are no longer present three years post-MI.</p> <p>As well, beta blockers are often poorly tolerated, resulting in a negative impact on a patient's quality of life.</p> <p>In regard to "CAD: Beta Blocker therapy – LVEF <40%," this is an appropriate measure. It is covered in the HF: Beta blocker therapy for LVSD below.</p> <p>Given the dramatic changes in treatment and diagnosis of MI, we recommend removal of this measure from the set, otherwise, we recommend that the measure undergo significant revision.</p>
HF: Beta Blocker therapy for LVSD	0083*	008	<i>No comments</i>
Cardiac Rehab Patient Referral from an Outpatient Setting	0643	243	<p>Patients are typically referred for cardiac rehabilitation from an inpatient setting, therefore some clinicians may not receive credit.</p> <p>The ACC will explore the possibility of extracting this data from the NCDR[®] CathPCI Registry[®] given that the corollary inpatient referral measure will not be valid for use in the MIPS program due its measurement at the hospital level.</p>

Ischemic Vascular Disease All or None Outcome Measure (Optimal Control) <ul style="list-style-type: none"> • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg • And most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated 	N/A	441	ACC initially requested this measure to be removed and replaced with MIPS 226: Tobacco Cessation Note that in the CQMC Cardiology measure set ad hoc review of 2021, the group discussed choosing either 0076, Optimal Vascular Care, MN Community Measurement, or Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (MIPS ID 441), Wisconsin Collaborative for Healthcare Quality. The ACC recommended the selection of #0076 since it is NQF-endorsed. It does not seem clear if it makes sense to give only credit for one measure with composite measures such as this one.
Advance Care Plan	0326	047	<i>No comments</i>
Preventive care and screening: BMI screening and follow-up plan	N/A	128	<i>No comments</i>
Use of High-Risk Medications in the Elderly	0022	238	Many cardiac medications are not considered high-risk. One exception might be digoxin since it is often prescribed indefinitely. There is a consequence that clinicians may wrongfully not perform well on this measure if a medication such as this is prescribed long-term.

Other Heart Disease MVP Quality Measures			
Quality Measure	NQF #	CMS #	ACC Comments
CAD Antiplatelet Therapy	0067*	006	Although this measure was originally proposed for this set but is now located in the Chronic Disease Management MVP, it is a guideline-directed therapy for this population. We suggest its inclusion in the Heart Disease MVP.
Controlling High Blood Pressure	N/A	236	We agree with the omission of this measure from the Heart Disease MVP.
Cardiac Stress Imaging Not Meeting AUC: Routine Testing After PCI	0671*	323	We agree with the omission of this measure from the Heart Disease MVP.
Statin Therapy for the Prevention and Treatment of CV Disease	N/A*	438	Although this measure is in the Chronic Disease Management MVP, ACC recommends retaining this measure in the Heart Disease MVP. Among cardiology measures, statin therapy has one of the greatest impacts on decreasing mortality and morbidity in patients with atherosclerotic CV disease. The evidence of benefit in those identified for statin therapy in this measure is strong and as the measure is not topped out, it represents an opportunity for improvement with substantial clinical benefit.

(2) Chronic Care MVP

The ACC requests clarification and further information as to CMS' rationale for including measures of coronary artery disease in the Chronic Disease Management MVP as they may also be applicable in the Heart Disease MVP. However, we are aware that CMS aims to attain MVPs that may either be broadly applicable to a variety of physicians, or to more specific condition or episode-based care.

While the ACC recognizes the strong need for effective management of chronic conditions, this MVP has the potential to capture such a broad range of clinicians that some settings may choose to report this set for all clinicians and not implement specific MVPs that would be more clinically relevant to specialty care.

B. APM Performance Pathways (APP)

The ACC appreciates CMS' proposal to maintain stability in the APP reporting requirements and measure set for CY 2022 as this will allow entities to prepare for the transition from Web Interface reporting to a new mechanism by the end of 2023.

C. Automatic Extreme and Uncontrollable Circumstances Hardship Exception for 2021 Performance Period

The COVID-19 PHE has been impacting cardiologists and the general House of Medicine since well before January 1, 2021, and is expected to remain in effect through at least the end of the calendar year. Although the rate of COVID-19 cases, hospitalizations, and deaths decreased in the early summer, unfortunately those numbers are again surging in part due to the Delta variant. As in 2020, clinicians on the front lines do not have time to focus on MIPS, and patient case mix is changed, and utilization will vary geographically as physicians in hot spots once again delay or cancel non-essential procedures. The ACC requests eligible clinicians and groups be held harmless from a MIPS penalty in 2021 as they continue to confront this PHE. The College asks CMS to make this determination sooner rather than later so physicians may prioritize patient care during this pandemic.

D. Performance Threshold

The ACC urges CMS to leverage the Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to lower the performance threshold from the proposed 75 points. While CMS states that the statute would otherwise progress towards full MIPS implementation and use of a prior year's mean or median as the performance threshold in 2022, the College understands the extraordinary circumstances of the COVID-19 pandemic warrant a change in course of action.

Prior to the start of the PHE, the performance threshold was 30 points. Jumping from 30 to 75 points considering the three years of disruptions to MIPS is unreasonable. As a result, **CMS should not move ahead with the proposed 75-point performance threshold and, instead, should establish a transitional policy that recognizes the impact of the COVID-19 PHE.**

E. Promoting Interoperability Performance Category Performance Period

i. Proposed Data Availability Requirement for MIPS eligible clinicians

In the proposed rule, CMS states MIPS eligible clinicians would need to ensure patient health information remains available indefinitely, with any encounter data with a start date after January 1, 2016. **While the College understands and appreciates the benefit a truly longitudinal health record can afford patients and providers, CMS should consider the costs associated with indefinitely storing data for all patient encounters.** While offices, hospitals, and other health care settings are used to storing patient data for a defined period of time under existing regulations, the indefinite storage of data can add substantial data storage costs to practices as well as require additional cybersecurity protections, especially for legacy IT and modalities.

ii. Modifications to the Public Health and Clinical Data Exchange Objective

CMS proposes making the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the performance period in CY 2022. **While the ACC agrees with CMS that the uneven adoption of electronic case reporting creates a public health vulnerability, the College is concerned that the technological infrastructure for required electronic case reporting does not exist at this time.** While CMS states that all 50 states have connected to the shared services platform, CMS states most states do not require electronic submission of case reports as part of their regulations and case reporting often occurs through outdated manual methods (for example, fax, email, or phone). Instead of requiring electronic case reporting for CY 2022, the ACC recommends CMS make this an optional objective for CY 2022, allowing all CEHRT utilizing eligible clinicians and institutions to ensure they have the ability to report electronically and require the objective for CY 2023.

iii. Proposed New SAFER Guides Measure

CMS proposes to add a new Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure to the Protect Patient Health Information objective beginning with the CY 2022 EHR reporting period. For this measure, an eligible hospital or CAH must attest to having conducted an annual self-assessment of all nine SAFER Guides, at any point during the calendar year in which the EHR reporting period occurs, with one “yes/no” attestation statement accounting for a complete self-assessment using all nine guides. This measure would be required for CY 2022, but not scored as a component of the Promoting Interoperability Program. **The ACC supports the development of measures that promote cyber security and EHR safety.**

The College also appreciates CMS proposing to make the measure required but not scored for the first year to allow for eligible hospitals and CAHs to prepare for compliance with the new measure. As recent events across the world, from Scripps Health to hospitals in Ireland have shown, cybersecurity is an essential component of delivering safe, effective care to patients. The ACC welcomes any initiatives designed to help increase awareness, promote best practices, and protect sensitive health data contained in EHR systems

F. Total Per Capita Cost (TPCC) and Medicare Spend Per Beneficiary (MSPB)

ACC continues to have concerns around the limited availability of cost measures but understands that until new cost measures are developed, the broader-focused measures such as Total Per Capita Cost (TPCC) or Medicare Spend Per Beneficiary (MSPB) are the only available measures by default.

The College appreciates CMS' efforts to improve both the MSPB and TPCC measures as evidenced by both public comment and the NQF endorsement process. However, we remain concerned with attributing broad-based downstream costs to clinicians or practices who provided care at an earlier point in time, particularly at the individual clinician level. Cost measures should only be attributed at the group/practice level or higher instead of with individual clinicians. It is difficult to account for the variety of influences on the costs of care, which may be attributable to the actions of an entire care team as well as a patient's individual environmental, social, and economic factors.

We continue to support the exclusion of clinicians from attribution based on their practice patterns or specialties and allowances for a specialty adjustment to account for the fact that costs vary across specialties and across clinician groups with varying specialty compositions. Cost measures should also risk-adjust for social determinants of health as appropriate and be within a clinician or group's reasonable ability to influence the outcome.

The ACC supports the notion that if a cost measure is unavailable or does not apply, the preference is to reweight the cost category to another performance category or categories over the utilization of the MSPB or TPCC measures. However, if an alternative cost measure must be included in the event that an episode-specific measure cannot be triggered, the ACC's preference is to utilize the MSPB Clinician measure and not the TPCC measure. The main factor in our preference for this measure over TPCC is that the cost of services provided to a beneficiary during an MSPB Clinician episode are calculated in the period immediately prior to, during, and following the beneficiary's hospital stay rather than the overall cost of care delivered to a beneficiary that focuses more on primary care. In addition, the measurement period is limited to 30 days after the procedure or event, rather than one year beyond the candidate event as with the TPCC measure.

G. Outcomes-Based Administrative Claims Measure

i. MIPS Quality Measure: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System

We appreciate CMS' initiatives to understand and improve quality for heart failure patients given the costs to care for such patients as well as the burden on the healthcare system. Admission rates are an important aspect of quality of care, and as such, we have feedback on the proposed outcomes-based administrative claims measure for the recently NQF-endorsed *Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System*.

The ACC agrees with the concerns raised during NQF review about attribution, the low reliability minimum sample size (21 cases) and reliability threshold (0.4), and the need for additional risk factors to be evaluated. Below, we outline our specific concerns with this measure and suggestions for improvement. **Prior to implementing this measure for scoring under MIPS, the ACC recommends that CMS work with Yale/CORE to address the following:**

- Finding the appropriate attribution for heart failure care and other chronic conditions is challenging and will not lead to a perfect algorithm. While MIPS was designed to cater to individual clinicians, attribution of the individual provider for complex conditions and complex systems of care, including heart failure patients, is difficult to achieve and does not accurately reflect patient outcomes.
- Many TINs in large organizations comprise both primary and specialty practices and therefore it is not entirely clear how attribution might be determined. This may be of concern, for example, with Advanced Practice Practitioners who are often considered primary care but may also be in a cardiology practice. In this scenario, if a cardiology-specific APP has the most patient touchpoints, attribution could fall within primary care while in fact the cardiology practice is driving costs. Another example is an electrophysiologist who sees an appropriately referred patient for a device and sees that patient twice in one year (e.g., the initial consultation, a follow-up visit), she will now "own" the heart failure care for the year over the primary care provider, based on attribution logic.
- Heart failure patients are often cared for by more than one cardiologist and may involve an entire care team, as well as caregivers outside of the usual spectrum of care. Additionally, further refinement around how inpatient and outpatient providers (e.g., cardiologists) are defined would be helpful.
- The Yale/CORE group are aware of socioeconomic stratification and validity issues, but it appears they are not receiving the data from CMS that they need. We recommend that CMS provide the necessary data so this may be addressed.
- Finally, conceptual language around planned admissions that may involve certain procedures such as revascularization, device implantation and ablation should potentially be carved out and categorized as episodes. These types of procedures may incur large costs in one year, but cost-savings could be realized in the timeframe beyond one year.

This is where defining a managed episode of care over which cost savings may be accrued would be helpful.

ii. Population Health Foundation Measures

The ACC acknowledges CMS' intention to design the MVPs as a pathway to future APM participation. While the College continues to express the concerns below regarding the use of these measures in a clinician-level program such as MIPS, we accept that introducing population-level measures around unplanned readmissions provides an opportunity for clinicians to become more familiar with these metrics which are increasingly used as part of risk-based payment models.

Prior to implementation of these measures as part of MIPS/MVP Foundation Layer measures, the ACC requests that CMS address the following measure-specific concerns which have been raised through the NQF endorsement process.

#3495, Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups:

Although this measure is endorsed by NQF and was finalized for inclusion in the 2021 rule, the ACC has concerns with this measure, including:

- Insufficient evidence to support attribution of this measure to clinician groups without developing a coordinated program or intervention led by health systems or hospitals. Attribution remains a concern as it is difficult to discern how multiple physicians may be assigned responsibility for a reduction in readmissions. Multiple clinicians are normally involved in a hospital environment.
- The impact of socioeconomic risk factors and how the measure performs under the MIPS benchmark methodology.
- Procedure categories should be evaluated carefully. For example, TAVR (or transcatheter aortic valve replacement) is an increasingly large driver of valve-related disorders, for which there is a defined therapy and low readmission rate. Lumping this procedure with "heart valve disorders" would not be appropriate and would make the category become too heterogeneous.
- The need for higher case minimums of patients to ensure higher reliability of the measure. The reliability ratings for clinicians in the cardiorespiratory and cardiac groupings were only moderate.
- Weak evidence in terms of a relationship of individual clinicians with the care in health systems, especially in those with a higher degree of hospitalists.
- Whether this is a true quality measure or simply a measure of utilization
- Whether hospital systems with integration perform at a higher level, disadvantaging smaller practices.
- Whether other policies such as the Stark Law, may have some influence in terms of care coordination and referrals; impacting performance on this measure.

#3597, Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions:

The ACC agrees with concerns outlined during the endorsement process, including less than desirable reliability thresholds and intraclass correlation coefficients for the minimum sample size/case volume, and the lack of inclusion of socioeconomic risk factors in the risk adjustment model and the adequacy of the risk model.

Understanding health outcomes at a broader level is critical to understanding and improving the quality of care, health outcomes, cost and resource use, reducing disparities, and engagement with patients and families. We recognize that the concept and construction of population health measurement faces numerous challenges, including its concept and definition, reliability and validity, data collection and analysis, and accountability.

iii. Proposed Process for Cost Measure Development by Stakeholders

Cardiologists continue to participate in cost measure development opportunities through CMS and Acumen, LLC. The ACC appreciates that CMS has established clinician-led workgroups to inform the development of these measures. CMS proposes to implement a process outside of this current workgroup structure to allow stakeholders to develop cost measures and expand the inventory of episode-based cost measures. While the ACC recognizes that this could potentially make the development of cost measures more efficient, we offer CMS the following considerations.

First, the ACC has long emphasized that cost measures must be linked with clinically appropriate quality measures in any performance program. As CMS identifies future cost measure topics, the Agency should prioritize categories that can be tied to clinical quality measures and not just focus on reducing utilization. Any cost measure developer should be asked to recommend associated quality markers that would align with a cost measure.

Second, CMS should ensure that clinicians lead the development of all cost measures. The ACC reiterates our appreciation of the Acumen clinical workgroup process which brings stakeholders representing various members of the care team to inform the development of measures. The Acumen staff have also been valuable in providing clinicians with expertise and guidance throughout the cost measure development process. Many clinician organizations have expertise in quality measure development, but not cost measure development. The ACC urges CMS to consider how to provide specialty societies with resources such as technical assistance from Acumen to support external cost measure development.

In addition, CMS must find ways to expand access to Medicare claims data so medical specialty societies can engage in cost measure development. Many organizations have had issues accessing claims data through the available ResDAC, Qualified Entity, and Quasi-Qualified Entity pathways; even when applications under these programs have been approved,

these pathways often offer permission for very limited use cases. Claims datasets may be available through third party organizations who have already obtained ResDAC approval; however, many specialty societies do not have the resources to obtain and analyze these expensive datasets. CMS should determine ways to allow broader access to usable Medicare claims data so that cost measure developers are not unintentionally limited to groups that can afford access to these data.

Finally, CMS should ensure transparency in cost measure development if external stakeholders are to develop measures. The ACC supports the current process where CMS announces proposed cost measure categories and issues a call for clinicians to apply for clinical workgroups related to each measure. This has allowed groups such as the ACC to inform various members with expertise related to the topic and encourage clinician involvement in the development process. When proposing new measures, the measure developer should be identified. CMS should explore ways to maintain this transparency and opportunity for early engagement.

iv. Subgroup Reporting

The ACC appreciates CMS' proposal to consider subgroup reporting under MIPS as a way for clinicians to report the most clinically meaningful measures to their practice. While the College strongly encourages this reporting structure as a way for specialist groups to report meaningful measures as part of a multispecialty group, we recognize that it may also result in administrative complexity. **The College supports CMS' proposal to begin subgroup reporting as a voluntary option and asks the Agency to continue evaluating whether clinicians and groups are prepared for mandatory subgroup reporting by the CY 2025 performance year.**

(1) Proposed Subgroup Reporting Limits

As CMS further explores subgroup reporting, we ask that the Agency determine the potential impact this may have on other policies and programs that rely on the use of a TIN for identification purposes, such as the Stark Law. While the creation of new TINs based on MVP may be feasible for some groups, limitations with current regulations impacting TIN structure may create challenges for others.

For example, CMS proposes that subsets of a group under the same TIN could form subgroups, but subgroups cannot be formed if clinicians are part of different TINs. Given the importance of engaging in care coordination under value-based payment models, some cardiology practices that manage a patient in the outpatient setting seek ways to align incentives with hospitalists and other care providers outside of the practice who may manage the patient during an acute care episode. Based on interpretations of the Stark Law, these practices have not been able to engage in such arrangements as assignment under different TINs prohibits recognition of these cross-setting teams as a "group practice" under current regulations.

The ACC recognizes that changes beyond this proposed rule may be needed to permit eligible clinicians in multiple TINs to form a subgroup or APM Performance Pathway (APP) group. The College asks that CMS explore how to address this scenario and continue to ensure that the introduction of TIN-based subgroup reporting does not create administrative complexity for clinicians and groups.

(2) Limiting Subgroups to a Single Specialty

CMS is considering whether subgroups should be limited to a single specialty and proposes the requirement that a subgroup be comprised of 75 percent of clinicians with the same primary specialty designation according to PECOS or Medicare Part B claims. Cardiology encompasses a variety of clinician types including general cardiologists, interventionalists, cardiac surgeons, electrophysiologists, and advanced heart failure and transplant specialists; each of these specialists may not always treat the same patient populations. In addition, the cardiology team also includes advanced practice professionals such as nurse practitioners and physician assistants who work closely with the physicians to manage patients. **The ACC urges CMS to consider whether this is a feasible threshold for cardiology, especially if additional MVPs in the cardiovascular space are developed.**

In addition, we recommend review of Section I.A.ii. of this comment letter (“Definition of Same Group”) for additional considerations regarding the complexity of PECOS and claims-based attribution for cardiology groups utilizing a team-based care approach between physicians and advanced practice professionals.

(3) MVP and Subgroup Public Reporting

CMS proposes to delay the public reporting of any MVP data on new Improvement Activities or Promoting Interoperability measures for one year after it is first included in the MVP. CMS proposes to delay the public reporting of new quality and cost measure data for two years after initial inclusion in an MVP. **The ACC strongly supports both of these proposals and appreciates CMS’ intention to ensure the accuracy of these data for public reporting before they are included in Physician Compare. The ACC also supports CMS’ proposal to delay all subgroup-level public reporting for one year as clinicians become familiar with this reporting structure.**

(4) Proposed Subgroup Eligibility – Participants in MIPS APMs

CMS states that APM Entities should not be eligible to form subgroups for MVPs or APM Performance Pathway (APP) participation because these entities are often comprised of multiple TINs and utilize multiple EHR systems.

While the ACC recognizes the potential administrative complexity of establishing subgroups under this structure, we strongly encourage CMS to continue exploring options for subgroup reporting by those who are part of an APM Entity. There are still many

clinicians who are part of a MIPS APM that is not considered an Advanced APM or are part of an Advanced APM but do not meet the Qualifying Participant thresholds. Thresholds for APM participation could be lowered to encourage further qualification and participation by MVP participants. Many of these APMs, such as the Medicare Shared Savings Program, utilize population-level, primary care focused quality measures that may not drill down to specialty-level performance. Exploring subgroup reporting options for MIPS APM participants would allow clinicians in these models to report the most meaningful measures to their clinical focus area.

H. Qualified Clinical Data Registries (QCDRs) & Third Party Intermediaries

In this proposed rule, CMS requires QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 MIPS performance period/2025 payment year; requires QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 MIPS performance period/2019 payment year) through the 2020 MIPS performance period/2022 payment year, to submit a participation plan as part of their self-nomination for CY 2023. Beginning with the CY 2023 MIPS performance period/2025 payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the Agency; Beginning with the 2024 MIPS performance period/2026 payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. CMS is also proposing rejection criterion to state that a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. The Agency is also proposing if a QCDR measure owner is not an approved active QCDR for a given self-nomination period, that QCDR measure will not be available for use. The inactive QCDR measure owner will have the option to transfer ownership of the QCDR measure to an active QCDR or agree upon terms set forth with the active QCDR allowing co-ownership of the QCDR measure. Finally, beginning with the 2022 MIPS performance period/2024 MIPS payment year, all QCDR measures must meet face validity. To be approved for the 2023 MIPS performance period/2025 MIPS payment year, all QCDR measures must meet face validity for the initial MIPS payment year for which it is approved. For subsequent years, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

As stated earlier in our letter, **The College supports CMS' proposal to allow QCDR's to support subgroup reporting but emphasizes the need for this to be a voluntary option and asks the Agency to continue evaluating whether clinicians and groups are prepared for mandatory subgroup reporting by the CY 2025 performance year.** While some entities and eligible program participants may be prepared for subgroup reporting by the CY 2025 performance, the ACC is concerned about the transitional burden this change poses to an already administratively burdensome process.

Given the COVID-19 PHE and collateral challenges new strains pose, the College remains concerned about the face validity testing requirement, as the testing process is 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 is also costly and taxing. Given the number of budget cuts that hospitals, offices, and other stakeholders across medicine are 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. **The ACC 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 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 QCDR-related requirements timeline back at least one year.**

Conclusion

The ACC appreciates the opportunity to comment on the CMS notice of proposed rulemaking regarding the CY 2022 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,

A handwritten signature in black ink, appearing to read 'Dipti Itchhaporia', with a stylized, elongated flourish at the end.

Dipti Itchhaporia, MD, FACC
President