AMERICAN COLLEGE of CARDIOLOGY

Heart House
2400 N St. NW, Washington, DC 20037
1-202-375-6000 | 1-800-253-4636 | Fax: 1-202-375-6842
ACC.org

June 3, 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes

Dear Administrator Oz:

The American College of Cardiology (ACC) appreciates this opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the FY2026 Medicare Hospital Inpatient Prospective Payment System (IPPS) proposed rule. The Colleges comments focus on Medicare-severity diagnosis related groups (MS-DRGs), the Transforming Episode Accountability Model (TEAM), the Inpatient Quality Reporting (IQR) measures, digital quality measures, and Medicare's Promoting Interoperability Program.

The American College of Cardiology (ACC) is a global leader dedicated to transforming cardiovascular care and improving heart health for all. For more than 75 years, the ACC has empowered a community of over 60,000 cardiovascular professionals across more than 140 countries with cutting-edge education and advocacy, rigorous professional credentials, and trusted clinical guidance. From its world-class JACC Journals and NCDR registries to its Accreditation Services, global network of Chapters and Sections, and CardioSmart patient initiatives, the College is committed to creating a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at *www.ACC.org* or connect on social media at @ACCinTouch.

Proposed Changes to Medicare Severity Diagnosis Related Groups (MS-DRGs)

Concomitant Single Valve Procedure with Open Surgical Ablation.

The ACC appreciates CMS addressing requests to review the MS-DRG assignments of concomitant open surgical ablation procedures. The College commented in support of the creation of the new MS-DRG 212 in the 2024 IPPS proposed rule. The ACC appreciated CMS recognizing the additional resources required for these concomitant procedures and applauds any effort to address the shortfall in reimbursement versus their cost when these, or any concomitant major cardiovascular procedures, are performed. However, we continue to believe that there should be

MS-DRGs to represent cases when an open aortic valve repair or replacement (AVR) procedure **or** a mitral valve repair or replacement (MVR) procedure are performed with any of the other concomitant procedures from MDC 05 that are included in the MS-DRG 212 GROUPER logic.

While the ACC agrees the presence of AVR and MVR together with another procedure requires enhanced resources, it is also the case that a trend exists where AVR plus ablation or MVR plus ablation require enhanced resources. Concerning MS-DRG 212 that addresses AVR/MVR procedures with concomitant procedures, as well as any concomitant major cardiovascular procedures, the College urges CMS to ensure that the incurred costs are adequately addressed so as to not disincentivize concomitant procedures which can be more efficient, more convenient, provide a better prognosis for the patient and could be more cost effective than the procedures being performed sequentially (i.e., during different hospital stays).

The College reiterates its encouragement of CMS to either amend the definition of MS-DRG 212 to address single valve replacement concomitant procedures or create additional MS-DRGs to address cases when an open aortic valve repair or replacement procedure or an open mitral valve repair or replacement procedure are performed with any of the other concomitant procedures from MDC 05 that are included in MS-DRG 212. Further, the College urges CMS to devise a broader, more inclusive, supplemental payment mechanism to facilitate incremental reimbursement when two major procedures are performed during the same hospital admission.

Transcatheter Aortic Valve Replacement (TAVR) Procedures for Aortic Regurgitation

The College understands the requestors intent to align patients receiving TAVR with severe aortic regurgitation with clinically similar heart failure patients in the heart assist system MS-DRG. However, upon review of the cost analysis demonstrated by CMS in this proposed rule, it appears the reassignment may not be appropriate at this time.

Percutaneous Coronary Atherectomy

The ACC appreciates the agency addressing requests to review the MS-DRG assignments of atherectomy procedures relative to MS-DRGs 323-325 for intravascular lithotripsy (IVL). The College supported the MS-DRG creation for IVL in FY2024 rulemaking and encouraged the agency to perform similar analysis as was done for IVL on the atherectomy procedures as these could also be considered what the agency referred to as "vessel preparation techniques." The ACC's contention was that upon this analysis evidence would be available to determine if the atherectomy codes should be kept as is, placed in a newly created MS-DRG or added to the IVL MS-DRGs.

Initially CMS stated that as the MS-DRGs 323-325 for IVL were so new, time was needed to obtain baseline data for the grouping before determining if the addition of atherectomy codes would be warranted. In this proposed rule, an analysis of said available data was performed. The analysis of cost and length of stay for atherectomy services relative to the services in its current MS-DRG assignment warranted the creation of new MS-DRGs for atherectomy services while not including

them in the IVL MS-DRGs.

The College appreciates CMS performing the requested analysis of atherectomy services. The College applauds CMS for recognizing the increased resources required for these services and supports the proposal to create new MS-DRGs for atherectomy services in the form of MS-DRGs 359 and 360, Percutaneous Coronary Atherectomy with Intraluminal Device with and without MCC; and MS-DRG 318, Percutaneous Coronary Atherectomy without Intraluminal Device.

Operating Room (O.R.) and Non-O.R. Procedures: Introduction of Paclitaxel-Coated Balloon Catheter Technology

The ACC appreciates the agency reviewing the request to reconsider the MS-DRG assignment of the sixteen procedure codes describing use of the AGENT Paclitaxel-Coated Balloon Catheter (DCB) technology from non-O.R. to O.R. placement. The College, however, disagrees with the proposal to maintain the DCB placement as a non-O.R. procedures.

DCB is a new percutaneous coronary intervention (PCI). Predecessor code 3E073GC's assignment as a non-O.R. service appears unhelpful since every other related service in the PCI family discussed in the rule is also considered an O.R. service. As the vessel preparation techniques discussed to allow DCB placement are O.R. services, it would only be consistent for the DCB service itself to also be an O.R. service. From a similar perspective, just as drug-eluting intraluminal device procedures (drug-eluting stents) are considered alongside non-drug-eluting intraluminal devices (stents); DCB should be categorized in the same manner as other dilation of coronary artery procedures (angioplasty). The FDA approval document repeatedly offers instructions on the DCB procedures with the phrase "as in all PCI procedures" in directing the appropriate precautions for these services which are definitively a part of the PCI family - all of which carry an O.R. designation.

The ACC urges CMS to designate the DCB procedures as O.R. and categorize them with the clinically appropriate services within the PCI MS-DRGs to maintain consistency throughout the Medicare program.

<u>Hospital Readmissions Reduction Program (HRRP)</u>

Proposal to Integrate Medicare Advantage (MA) Beneficiaries into the Cohorts of the Hospital Readmissions Reduction Program (HRRP) Measure Set

We support the proposal to integrate Medicare Advantage (MA) beneficiaries into the HRRP measure set beginning in FY 2027. This change will improve the representativeness of the measures and reflect the growing proportion of MA enrollees in the Medicare population. As the MA cohort continues to expand, including these beneficiaries will better ensure that the readmission measures convey the full experience of all Medicare patients.

CMS may want to consider stratifying performance results by payer type, comparing MA and FFS populations, and to ensure that MA encounter data are complete, reliable, and timely. This is essential to prevent hospitals from being unfairly penalized due to discrepancies in data quality between the two populations. Reports that some MA plans may have been including a favorable selection of healthier patients and manipulating risk scores through down-coding or other strategies have been concerning. These activities could distort readmission rates and create an uneven playing field when comparing MA to FFS performance.

We also recommend that CMS phase in these changes gradually by first providing confidential reports before any public release of performance results. CMS should actively engage clinical experts throughout the refinement process to validate the methodology. Releasing revised results without these safeguards may lead to unintended volatility in performance scores that do not reflect true differences in care quality, which could undermine trust in the program.

Overall, we commend CMS for implementing a number of adjustments to the program, including risk adjustment data validation, medical record audits, ongoing refinement of the HCC model, and now the proposed use of ICD-10 codes.

Proposed Use of Individual ICD-10 Codes for Risk Adjustment in the HRRP

The ACC supports CMS's effort to improve risk adjustment by transitioning from HCC groupings to the use of individual ICD-10 codes. We agree that accurate and clinically meaningful risk adjustment is important to fair performance measurement, particularly in programs like HRRP that tie quality measures to payment. Using individual ICD-10 codes offers the advantage of increasing precision in clinical care and measurement, which is highly relevant for high-variability conditions such as heart failure and coronary artery disease. It also better aligns with current documentation practices, allowing for more accurate modeling and benchmarking. Furthermore, it may improve the model's ability to distinguish between hospitals serving more complex and socially vulnerable patient populations.

However, CMS should proceed carefully and ensure transparency in the development of the new models. We recommend CMS clearly document the rationale and process for selecting and grouping ICD-10 codes within the risk model, so that clinical stakeholders can assess whether the model aligns with real-world care. CMS should also conduct clinical validation and extensive external testing before any public reporting, with particular focus on high-impact cardiovascular conditions like acute myocardial infarction (AMI), heart failure (HF), and coronary artery bypass grafting (CABG). The use of these codes means that accuracy and consistency, which can vary widely across institutions, is of utmost importance. Large systems with various coding teams and differences in documentation practices may experience performance volatility that is not reflective of actual quality differences. We recommend CMS monitor for unintended consequences and provide transparency around which codes are most influential in risk models. Regular updates and detailed documentation should be provided to ensure that providers understand how performance is being measured, and risk is being adjusted.

In addition, we recommend implementing a transition period during which HCC-based and ICD-10-based risk models are reported in parallel to help stakeholders understand the operational impact of the change. Performance analyses can be broken down by condition, hospital size and type, and patient demographics to detect and mitigate any unintended differences in the resulting performance ratings.

Removal of COVID-19 Exclusion

We understand and support CMS's rationale for removing the COVID-19 exclusion from the HRRP beginning in FY 2027, given the shift in the status of COVID-19 from an acute public health emergency to a manageable endemic condition. CMS should ensure that updated risk adjustment models fully account for the long-term clinical consequences of COVID-19 and potential differences in post-acute outcomes, particularly for cardiovascular patients. Patients with prior COVID-19 exposure may have long-term complications (e.g., cardiovascular, pulmonary, renal) that increase the likelihood of readmission. If these are not properly accounted for in the updated risk models, hospitals treating a higher share of post-COVID patients could be unfairly penalized.

Additionally, we recommend that CMS provide greater transparency around the updated modeling and allow for a transitional period with confidential reporting to minimize unintended financial penalties. Accurate attribution and risk stratification remain essential to ensure that readmission measures reflect true differences in care quality, not underlying differences in patient populations.

Proposed Removals in the Hospital IQR Program Measure Set

Proposed Removal of the Hospital Commitment to Health Equity (HCHE) Measure

We urge CMS to reconsider the proposed removal of the Hospital Commitment to Health Equity (HCHE) measure from the Hospital IQR Program. While we understand CMS's intent to reduce reporting burden, this structural measure plays a unique and foundational role in signaling the importance of organizational leadership and systems-level commitment to equity. Health equity is not merely an aspirational goal; it is a strategic imperative that underpins clinical outcomes and population health. The HCHE measure incentivizes institutions to establish the infrastructure necessary to identify, monitor, and act upon disparities in care delivery. Instead of removing the measure entirely, we encourage CMS to explore refinements such as adjusting the scoring methodology or adopting a tiered attestation framework to better balance burden with meaningful accountability.

Proposed Removal of SDOH Screening Measures (SDOH-1 and SDOH-2)

We encourage CMS to retain the Screening for Social Drivers of Health (SDOH-1) and Screen Positive Rate for Social Drivers of Health (SDOH-2) measures in the IQR Program. Social drivers of health, including food insecurity, housing instability, and transportation access, are well-documented determinants of cardiovascular outcomes and broader health disparities. Although we acknowledge concerns around the resource burden of implementing these measures, we believe their

continued inclusion is vital for encouraging health systems to integrate non-clinical determinants into care delivery strategies. These measures are among the few nationally reported metrics that reflect hospitals' recognition of upstream health needs, particularly for patients at heightened risk of adverse outcomes due to social vulnerability.

Rather than eliminate these measures, we encourage CMS to consider several strategies to support their continued implementation and impact. This includes providing technical assistance to help integrate screening into electronic workflows, exploring options to stratify reporting by patient demographics to better assess equity impact, and offering a confidential reporting option to facilitate iterative improvement before public reporting. We also recommend that CMS seek opportunities to collaborate with states, providers, patients, community organizations, and other stakeholders to develop and implement effective strategies that support the measures' goals.

TEAM Quality Measure Set and Hybrid Hospital-Wide Readmission Measure Alignment

As cardiovascular clinicians, we appreciate CMS's ongoing efforts to align quality measurement with meaningful clinical outcomes and to streamline reporting burden through integration with existing programs such as the Hospital IQR Program. TEAM presents an important opportunity to enhance quality-based payment, particularly for acute surgical and cardiovascular episodes of care.

We understand the intent to incorporate the Hybrid Hospital-Wide Readmission (HWR) measure into TEAM's performance year 1, given its ability to risk-adjust readmissions using both claims and EHR-derived clinical data. We agree that aligning TEAM's use of the Hybrid HWR measure with the Hospital IQR Program's timeline and submission allowances ensures consistency and reduces confusion among providers participating in both programs. This alignment also acknowledges current operational challenges with data completeness and EHR functionality across hospitals. However, while many hospitals have voluntarily reported the Hybrid HWR measure in previous cycles, mandatory reporting with a 70% threshold and new linking variable requirements could still pose logistical and workflow challenges. We encourage CMS to allow a transition period with confidential feedback reports before linking Hybrid HWR performance to payment. This will help mitigate any unintended financial penalties stemming from variability in EHR infrastructure or data availability rather than differences in quality.

From a cardiology perspective, patients hospitalized with conditions such as heart failure, myocardial infarction, or undergoing CABG surgery are often medically complex with multifactorial reasons for readmission. We recommend that CMS explore additional stratification or condition-specific refinement of the Hybrid HWR measure to better reflect clinical realities in specialty care. CMS should also address several implementation risks that could disproportionately impact cardiologists or other specialists practicing within large, integrated health systems. Many hospitals, particularly large academic or tertiary care systems, manage cardiovascular episodes through multidisciplinary teams. In these settings, readmissions and outcomes often reflect shared responsibility across hospitalists, proceduralists, intensivists, and outpatient cardiologists. The HWR measure may struggle to accurately attribute performance to any one specialty or provider group, leading to potential differences between clinical accountability and performance penalties or rewards. CMS

should assess and clarify how attribution methodology will be applied, especially when specialists are involved only during certain stages of care. We also question whether hospital-wide readmission rates truly reflect the quality of care delivered, or whether they serve primarily as a measure of care utilization. It is important to recognize that larger, integrated hospital systems tend to perform better on readmission metrics, potentially disadvantaging smaller or rural hospitals unless adjustments are made to reflect differences in care environments.

Patient-Reported Outcome-based Performance Measures (PRO-PMs)

Cardiologists support the development and inclusion of PRO-PMs specific to cardiovascular procedures and medical management (e.g., PCI, EP ablation, device implantation). Their absence limits the ability to truly capture patient-centered outcomes in this domain. Therefore, we support CMS's effort to expand the use of PRO-PMs in the TEAM model. Cardiovascular procedures and episodes frequently involve complex decision-making and significant patient anxiety. Post-discharge symptom burden, medication side effects, and procedural understanding are meaningful aspects of care quality that PROs could capture. These measures represent a vital step toward including the patient voice in assessing healthcare quality, especially in procedures where post-discharge communication and recovery play a critical role in outcomes.

Information Transfer PRO-PM

We believe the Information Transfer PRO-PM is relevant to patient and cardiovascular care, where procedures such as diagnostic catheterizations, PCI, or device implantations may be performed in the outpatient setting. These episodes often rely heavily on the clarity of post-discharge instructions, medication adherence, and timely follow-up, all of which depend on effective communication. Therefore, we cautiously support CMS's proposal to include this measure beginning in Performance Year 3, allowing hospitals time to build familiarity and refine workflows before scores impact payment. However, CMS should provide technical guidance, standardized tools, and learning collaboratives in the lead-up to reporting.

One caution is that patient understanding may be influenced by factors beyond provider control, such as health literacy, language barriers, or other influences. Many cardiovascular patients are older, medically complex, and face barriers like low health literacy or language access, factors not accounted for in the current unadjusted design. Also, while the measure is described as broadly applicable, CMS should clarify whether and how it will apply to outpatient cardiovascular episodes if those are added in future expansions of the model. The measure was developed and tested primarily in hospital outpatient departments, therefore raising questions about its applicability to other settings. Any PRO tool must be clinically tailored to ensure relevance and actionable feedback. Implementation of this type of measure in a value-based model tied to payment introduces higher stakes and will require more preparation and internal tracking.

Approach for When TEAM Participant Has No Quality Measure Performance Data

We appreciate CMS's recognition that some TEAM participants may not have sufficient quality data during the first performance year due to timing issues or elective participation in eCQMs. Assigning a neutral quality measure score of 50 appears to be a fair and practical interim solution that avoids penalizing providers who may be delivering high-quality care but lack reportable data due to structural constraints. This policy will be especially important for new hospitals or for episodes where clinicians in large health systems may have little control over which measures are selected for IQR reporting (e.g., decisions centralized at the system level).

To improve the fairness and transparency of this approach, we offer several suggestions. First, CMS should distinguish between the causes of missing data. There should be a clear difference between hospitals that are unable to report due to structural or timing factors, such as newly established facilities, and those that opt not to report or underperform in data collection. A tiered scoring approach could be considered: for example, hospitals with justifiable low volume or new operations might receive a neutral score of 50, while those that opt out of reporting discretionary measures, such as eCQMs, without sufficient justification could receive a lower score (e.g., 25). Second, CMS could encourage transparency by publishing whether a hospital's neutral score results from insufficient volume, new hospital status, or non-reporting. This would promote accountability without unfairly penalizing organizations, particularly large systems that may not report uniformly across settings. Third, TEAM participants should be allowed to submit optional supplemental documentation in advance if they anticipate a lack of quality data. This would help justify the assignment of a neutral score and support data integrity. Finally, CMS should consider the impact on the Composite Quality Score (CQS), especially in integrated systems where cardiologists and other specialists often do not control measure selection or EHR configuration. In these cases, missing PROs or hybrid measure data, particularly when EHR data are not yet integrated, should not disproportionately affect the hospital-level CQS in ways that clinicians cannot reasonably influence.

Potential concerns for cardiovascular clinicians include attribution complexity and data infrastructure gaps. For team-based specialties like cardiology, readmission rates and certain patient safety events may not be clearly attributable to any one clinician or even a specific service line. Missing data resulting from attribution challenges or low denominator cases should not trigger unfair scoring. Additionally, there are concerns regarding data infrastructure gaps. Many outpatient cardiovascular episodes, such as PCI and device procedures, are not currently part of mandatory quality reporting. If future TEAM model expansions include these procedures, CMS should be cautious about penalizing hospitals that do not yet have EHR infrastructure in place to capture PRO-PMs or hybrid data.

Comment on Proposed Removal of Health Equity and Social Needs Elements from TEAM

As cardiovascular physicians committed to advancing equitable, high-quality care across all populations, we are concerned about CMS's proposal to remove the health equity plan and health-related social needs (HRSN) data reporting elements from the TEAM model.

We strongly urge CMS to reconsider this proposal. Cardiovascular disease remains a leading cause of death in the United States, with persistent disparities in incidence, treatment, and outcomes among historically marginalized and underserved populations. These disparities are well-documented across racial and ethnic groups, rural populations, and individuals with low socioeconomic status, and they are not driven solely by clinical factors. Instead, social determinants such as housing instability, transportation barriers, food insecurity, and limited access to preventive services are consistently linked to worse outcomes, higher readmission rates, and greater healthcare costs, particularly in acute and post-acute cardiovascular episodes.

TEAM, as a payment and care redesign model, offers a valuable opportunity to address these drivers of inequity. Voluntary submission of health equity plans and HRSN data would help CMS and participants identify where disparities exist, tailor care redesign efforts to patient needs, and develop interventions that reduce avoidable complications and readmissions. Collecting this data is not a burden but an investment in targeting resources efficiently and effectively. It also aligns with the long-term goals of value-based care which leads to improving patient outcomes while reducing cost and inefficiency.

We agree that participant burden should be minimized in any mandatory model. However, instead of eliminating these data elements entirely, we recommend CMS explore options to streamline data collection, provide templates or standard screening tools, and align data collection with existing reporting efforts (e.g., Z codes or EHR-based fields). Furthermore, CMS could allow reporting through existing infrastructure or partner with quality collaboratives to reduce administrative complexity. While we respect the need to align with current policy priorities, we believe that removing health equity elements will compromise CMS's ability to identify meaningful differences in care, evaluate the impact of TEAM across diverse populations, and support systemic care improvement.

In conclusion, we think CMS should maintain voluntary collection of health equity and HRSN data, invest in reducing data collection burden, and retain definitions that enable future advancement of equity in care delivery. TEAM should not take a step back from these essential elements of value-based care.

<u>Proposed Quality Data Reporting Requirements for Specific Providers</u>
<u>Toward Digital Quality Measurement in CMS Quality Programs – Request for Information</u>

As part of the proposed rule, HHS seeks comments on the anticipated approach to the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting. The College agrees with HHS that having immediate access to electronic health information, in near real-time, supports quality measurement efforts, provides the ability to use these data for patient care considerations, and may lead to improved clinical outcomes. It is important to note that while there has been considerable progress in the development and utilization of FHIR-based application programming interfaces (API) to assist with the standardized submission of quality reporting data elements, **there is still considerable work to**

be done. As this process continues, the ACC stands ready to work with HHS and other regulatory agencies to help progress standardization and interoperability efforts.

In previous requests for information and rulemaking, HHS has stated the intent to transition to full digital quality measurement by 2025. **While the College was encouraged by the urgency and dedication to evolving how digital quality measurement takes place, the ACC expressed the need for more measured approaches that take into consideration the reality of current and near-term measure development and reporting processes.** As HHS notes in the RFI, multiple standards are currently used to report electronic clinical quality measures (eCQMs, making it a challenging and burdensome process.

Previous experience partnering 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 Disease Registries (NCDR) has helped inform the College about the resources required to successfully crosswalk quality measures. We are aware that at least one cardiology-related eCQM, such as *Statin Therapy for the Prevention and Treatment of Cardiovascular Disease* (CMS #347), has been translated into a FHIR-based specification.

It is notable that approximately half of the top 10 measures most frequently reported from the cardiology MIPS measure set are eCQMs, including measures such as #236 (Controlling High Blood Pressure) and #130 (Documentation of Current Medications). While this demonstrates meaningful progress in digital measure adoption, it still falls short of CMS's earlier stated goal of achieving 100% eCQM reporting by 2025. The College believes that many cardiology measures used or stewarded by cardiologists are still in QDM or non-FHIR formats. This suggests that significant barriers remain, particularly around data capture, EHR integration, and workflow alignment, which must be addressed before broader adoption is feasible. **As HHS continues to prepare for the transition to digital quality measurement, it is imperative that any policies 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.**

In the request for information, HHS considers the requirement that all measures proposed for addition to CMS programs be specified in FHIR. While the ACC appreciates the commitment to the development of standardized measures, the current reality is measures utilized by the entire cardiovascular team exist in multiple standards, some of which are commonly used and others of which are proprietary standards developed in close consultation with hospitals and other reporting sites. It will take extensive time and resources to make these measures FHIR-based.

As the experience with the CMS Innovation Center's Enhancing Oncology Model has shown, it can take years from development to reporting at the site of care for specialty clinical data elements. As HHS moves towards the implementation of these measures, HHS should assess why full transition to eCQMs has not occurred as anticipated and work with specialty societies to develop a more realistic and flexible pathway for increasing digital measure use without disrupting high-value reporting mechanisms already in place.

HHS also asks for input on the timeline for transitioning to FHIR-based reporting for clinical measures. HHS indicates they are considering proposing a transition period during which healthcare providers may report using either QDM- or FHIR-based eCQMs and would consider a two-year reporting option before any mandated reporting requirements. **While the College appreciates the intent behind a transition period and a minimum of 24 months from the effective date of a FHIR-based eCQM reporting option using ONC Health IT Certification Program criteria to support quality program submission provide sufficient time for implementation, if HHS were to move forward with a proposal for CY 2027 and a mandated reporting period starting in CY 2029, the College would currently have difficulty meeting this timeline.**

As previously stated, the College lacks the resources to fully crosswalk measures to FHIR-based standards and a lack of definitive direction from agencies prevents the ACC from investing necessary resources in this transition. **Instead, HHS should provide medical societies, clinical data registries, and measure stewards with specific direction and sufficient warning before implementing major changes.** After sufficient warning, HHS could proceed with a transition period allowing either QDM or FHIR-based reporting, allowing for additional testing and transition time. This will allow all necessary stakeholders to have a clearer understanding of the requirements and specifications they must build around and allow providers the time to prepare for a new reporting paradigm. An example of this proposed timeline could be HHS announcing intent to transition to FHIR-based reporting by CY 2032 in the CY 2027 rulemaking cycle, with a two-year dual reporting period for reporting years 2030 and 2031.

HHS should also explore ways to reduce the complexity of the submission process, including offering centralized platforms or leveraging specialty society registries that already collect high-quality data. In many cases, registries and specialty societies can offer more accurate, clinically nuanced data that reflects the complexity of care. Many data elements used in current eCQMs are either not routinely captured in structured EHR fields or are captured inconsistently across systems. Specific clinical findings, procedure indications, and shared decision-making elements are often documented in free text or within registries, rather than in discrete EHR fields that align with QI-Core profiles. Registries, however, are nimble and adaptable and can quickly add fields to capture additional data. **HHS should permit the use of validated registry or third-party vendor data where appropriate, especially when it enhances the accuracy and utility of performance measurement.**

Additionally, attribution logic can be particularly challenging to represent accurately in FHIR, especially for measures that span multiple providers or care settings. Without standardization of these data inputs across EHR vendors and sufficient time for mapping, validation, and workflow integration, the transition could place a significant burden on clinicians and health IT teams. **As HHS considers this shift, we urge close collaboration with specialty societies and registries to identify which measures are most feasible to convert and to ensure that any transition maintains clinical accuracy and usability.**

Proposed Changes to the Medicare Promoting Interoperability Program

Proposal to Modify the Security Risk Analysis Measure

HHS proposes to modify the existing Security Risk Analysis measure to require eligible hospitals and CAHs to attest "yes" to having conducted security risk management as required under the HIPAA Security Rule implementation specification for risk management. Currently, the Security Risk Analysis measure only requires eligible hospitals and CAHs to attest "yes" or "no" as to whether they have conducted or reviewed a security risk analysis and does not require the eligible hospital or CAH to.

The proposed changes to this measure would align with the proposed modifications to the HIPAA Security Rule in RIN 0945-AA22 *HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information*. Under that proposed rule, HHS clarifies the actions, such as deploying safeguards, that would be required to meet the HIPAA Privacy Rule requirements. Likewise, modifying this measure would require eligible hospitals or CAHs to conduct a security risk analysis to receive credit. **The College supports efforts by HHS to better protect protected patient health information (PHI), including modifying the Security Risk Analysis measure.**

Proposal to Modify the Safety Assurance Factors for EHR Resilience (SAFER) Guides Measure

HHS proposes to modify the SAFER Guides measure by requiring eligible hospitals and CAHs to attest "yes" to completing an annual self-assessment using all eight 2025 SAFER Guides to be considered a meaningful EHR user, beginning with the EHR reporting period in CY 2026. The College has supported efforts by HHS to improve cybersecurity, including creating the SAFER Guides measure. **The ACC thanks HHS for working to update the measure to align with new SAFER guides that focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience.** By doing so, HHS can continue to incentivize the implementation of best practices that increase cybersecurity preparedness.

Proposal to Modify the Public Health and Clinical Data Exchange Objective: Adoption of an Optional Bonus Measure for Public Health Reporting Using the Trusted Exchange Framework and Common Agreement (TEFCA)

HHS proposes adding an optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a public health agency (PHA) that occurs using TEFCA. Under this measure, an eligible hospital or CAH that signs the Framework Agreement, meets their eligibility requirements, and submits health information using TEFCA and is in active engagement with a public health agency would be eligible for the bonus points.

While the College supports any efforts to incentivize continued adoption of interoperability

capabilities such as TEFCA, the College is concerned that the elimination of entities that are in pre-production or validation (Option 1 under the current measure) will reduce the applicability of this measure. If the goal is to continue to incentivize signatories to the Framework Agreement and encourage electronic health information exchange via TEFCA to PHAs, HHS should continue to allow for Option 1 eligible hospitals and CAHs to claim this measure.

Currently, TEFCA only has 9 designated Qualified Health Information Network® (QHINs™) with another currently onboarding. While these QHINs do provide access to vast amounts of information electronically and cover tens of millions of patients, TEFCA is still in its infancy and signatory participation is somewhat limited, especially among smaller or rural eligible hospitals and CAHs. These entities may still be examining participation as TEFCA adoption grows and allowing them to claim the measure while in pre-production or validation can help to continue to incentivize this adoption process. **The College encourages HHS to reconsider removing Option 1 from the Public Health Reporting Using TEFCA measure until TEFCA adoption reaches a mature, steady state.**

RFI Regarding Data Quality

In the proposed rule, HHS seeks comments from stakeholders to encourage and support the use of modern technologies and standards to ensure data are usable, complete, accurate, timely, and consistent. In the request, HHS correctly identifies the risks that come with low-quality data. HHS defines data quality as "the degree to which health information is accurate, complete, timely, consistent, and reliable." As noted, poor data quality poses direct threats to patient safety, especially when providers treat patients based on inaccurate or incomplete information. HHS also noted "Poor quality data also poses risks beyond health care delivery and administration because health care data captured by EHRs serve as the foundation for public health reporting and clinical research using real world evidence, widespread deficits in data quality can adversely affect clinical innovation and public health decision-making".

The College strongly agrees with the sentiment that complete, accurate and timely data is essential treating patients and encouraging the development of high-quality public health reporting and clinical research, which are essential to clinical innovation and public health decision-making. As such, **the ACC was disappointed to see a recent enforcement discretion memo from the Assistant Secretary for Technology Policy (ASTP)/ Office of the National Coordinator for Health IT (ONC) directing ONC-Authorized Certification Bodies (ACBs) to not take enforcement action against certified Health IT modules that do not demonstrate the capability to categorize data on individuals based on several United States Core Data for Interoperability (USCDI) version 3 data elements, including sexual orientation and gender identity.**

As HHS recognizes, complete and accurate data is essential for health care professionals and researchers to make accurate and timely decisions. By exercising this enforcement discretion and allowing certified Health IT vendors to discontinue use of these important data elements, ASTP/ONC risk health care professionals, patients, and researchers having access to incomplete

data that could be incredibly important in providing an accurate diagnosis or developing a break-through finding. **While the ACC understand that HHS and ASTP/ONC are bound to follow Executive Order (EO) 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," the College implores HHS and ASTP/ONC to consider alternative methods to ensure that data robustness remains a core component of the Health IT certification program.**

Proposed Changes to the Transforming Episode Accountability Model (TEAM)

The College acknowledges the importance of CMS progression of the transition from fee-for-service to value-based care models. The TEAM demonstration project is a significant step in testing mandatory focused episode of care models in the inpatient and hospital outpatient settings. The ACC appreciates that CMS supports the importance of specialist care in the progression towards value-based care through continued refinement of the TEAM model. The College is encouraged by the agency's learning from the Bundled Payment for Care Improvement Advanced (BPCI-A) and the Comprehensive Care for Joint Replacement (CJR) and believe that the mandatory nature of TEAM is appropriate based on insights from these previous models. However, the College remains concerned about potential impacts of the TEAM including:

- The negative impact on hospitals and health systems particularly those in low-income and underserved communities in tenuous financial scenarios with only a single year of no-downside risk.
- Timely and actionable data from CMS must be provided to all TEAM participants along with step-by-step recommendations and/or guidance for improvements when possible.
- While the current proposal entices the TEAM participants to manage post-surgical care and incentivizes patients with telehealth access and other services, such arrangements can disrupt or fracture the original/pre-surgery patient-clinician relationship.

TEAM Participation tracks

It is important to remember that the current state of America's hospitals and health systems are financially fragile. While some are thriving and run efficiently others are struggling to survive and provide necessary care for their communities. In the past 2 years, there have been numerous hospitals closed and hospital employees laid off. The College appreciates that CMS is striving to protect hospitals that might be particularly vulnerable by stratifying risk pathways for Safety Net Hospitals, Rural Hospitals, Sole Community Hospitals, Essential Access Hospitals, and hospitals previously designated as Medicare Dependent. ACC believes that for more financially vulnerable participants it is vital that CMS and the Center of Medicare and Medicaid Innovation (CMMI) provide timely and usable data regularly to support the participating hospitals to ensure their financial stability. Additionally, the College encourages CMS' continued assessment and fluidity in future rulemaking around track participation to assure that these TEAM participants are not doomed to financial loss throughout the model test period.

Hierarchical Condition Categories and Risk Adjustment

The ACC appreciates the expanded proposed 180-day lookback period to risk adjust for patient acuity using previous fee-for-service claim data. However, the College would encourage the agency to further extend the lookback period to a year. While previous models have used various lookback periods, we believe a full year lookback period provides a more complete picture of patients' health when they enter the model. A full year lookback would provide better prediction of a level of episode spending which may be outside of the control of the TEAM participating hospitals and clinicians.

The College supports CMS' proposed update to HCC version 28. The more detailed data in HCC v28 will provide patient information that is useful to researchers and CMS as TEAM data informs future models. The College believes the proposed list of HCCs for coronary artery bypass graft (CABG) episodes is appropriate and should provide a simplified risk adjustment method. The College believes that updated HCC v28 is important as a current and consistent hierarchical condition category version should be used for the duration of the model to best assess year over year changes.

Low Volume Hospitals

The College encourages CMS to set a specific number (per episode category) which would determine whether a hospital has low volume status and financial protections. Given the mandatory nature of TEAM and the financial consequences to hospitals which may be on the cusp of low volume status, the College encourages CMS to set a low volume threshold well above the 41 clinical episode minimum volume threshold during the 4-year baseline period used in BPCI Advanced. Additionally, we believe the original proposed low volume threshold of at least 31 total episodes across all episode categories in the baseline period is far too low and makes hospitals which perform low volumes of TEAM episodes vulnerable to financial harm. While Track 1 is an option for all TEAM participants in year one, that track is optional and does not specifically provide necessary guaranteed protection against potential low volume financial vulnerability.

Referral to Primary Care Services

The 2025 Hospital Inpatient PPS final rule requires the TEAM participants to include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, or prior to discharge from an anchor hospitalization or anchor procedure. Along with promoting prevention, Medicare is prioritizing the post-procedure continuity of care. The ACC agrees with the overall intent to bolster primary care for these patients and is intensely interested in the integration of primary care and specialist care in value-based arrangements. However, we question the viability and usefulness of a primary care referral directly following these intensive specialty-focused procedures and hospitalizations. A patient's need of a coronary artery bypass graft is the result of a chronic coronary condition, they would certainly benefit from ongoing care from cardiovascular specialists.

While most CABG procedures are performed by cardiovascular and thoracic surgeons, the patient's follow-up care is often handled and directed by cardiologists and their cardiac care teams. If a referral requirement is needed, the College would strongly recommend the referral should be made to the ordering or primary follow-up physician rather than exclusively a primary care clinician.

Conclusion

Thank you for your consideration of these comments from the ACC. The College appreciates the thought and effort that go into rulemaking and looks forward to future engagement on topics included in this and other rules and policy discussions. Please contact Matthew Minnella, Associate Director, Medicare Payment Policy at mminnella@acc.org if additional information would be helpful.

Sincerely,

Christopher M. Kramer, MD, FACC
President, American College of Cardiology