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June 9, 2024

The Honorable Chiquita Brooks-LaSure
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 and Medicaid Programs and the Children's Health Insurance 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 2025 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the FY 2025 Medicare Hospital Inpatient Prospective Payment System (IPPS) for acute care hospitals and other policies addressed in this proposed rule. The Colleges comments focus on the Medicare-severity diagnosis related groups (MS-DRGs), new technology add-on payments policy (NTAP), the Transforming Episode Accountability Model (TEAM), Medicare Promoting Interoperability Program, and the Inpatient Quality Reporting (IQR) measures.

The American College of Cardiology (ACC) is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source of professional medical education for the entire cardiovascular care team since 1949, and now with more than 56,000 members from over 140 countries, the ACC credentials cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. Through its world-renowned family of JACC Journals, NCDR registries, ACC Accreditation Services, global network of Member Sections, CardioSmart patient resources and more, the College is committed to ensuring a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at www.ACC.org or follow @ACCinTouch.

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

II.C.1.b Requests to Modify GROUPER Logic: MS-DRG 212 Concomitant Aortic and Mitral Valve Procedures, and MS-DRGs 323-325 Coronary Intravascular Lithotripsy with Intraluminal Device with MCC, without MCC and without Intraluminal Device

The ACC appreciates CMS addressing requests to review the GROUPER logic of MS-DRG 212 Concomitant Aortic and Mitral Valve Procedures. The College commented in support of the creation of the

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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 MS-DRG 212 should represent cases when an open aortic valve repair or replacement procedure **or** a mitral valve repair or replacement procedure are performed with any of the other concomitant procedures from MDC 05 that are included in the proposed 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 understands the agency's desire to allow more time before making adjustments to the newly created MS-DRG 212. The College reiterates its encouragement of CMS to perform the analysis necessary to consider the MS-DRG representing 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.

The ACC appreciates the agency addressing requests to review the MS-DRG assignments of atherectomy procedures relative to the newly created MS-DRGs 323-325 for intravascular lithotripsy (IVL). The College supported the MS-DRG creation for IVL 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. It appears that the formal requests submitted to CMS specifically called for the atherectomy codes to be moved to the IVL MS-DRGs.

In considering the proposal to include atherectomy codes in the IVL MS-DRGs the agency notes that the root operation used to describe atherectomy is extirpation, while the root operation used to describe IVL is fragmentation. CMS further notes that these are not the same and do not warrant similar MS-DRG assignments. The CMS ICD-10-PCS Reference Manual defines extirpation as "taking/cutting out solid matter" and fragmentation as "breaking solid matter into pieces without removal." As the most common types of atherectomy do not take out, cut out or remove plaque, the procedure is, in most cases, more accurately described as fragmentation. In the FY2024 final rule the agency explained their stance that rotational and orbital atherectomy have a root operation of extirpation because the calcified material is cut up into small particles that are "removed from the blood stream by the normal hemofiltration process." We would challenge that logic as the procedure itself is not removing the material in question and further, this normal hemofiltration process would also then apply to the calcified material broken up in fragmentation

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procedures.

The College understands the agency's desire to allow more time before making adjustments to the newly created IVL MS-DRGs (323-325). The College reiterates its encouragement that CMS do a full analysis of the atherectomy codes to determine whether an adjustment of the MS-DRG reimbursement is needed, a new MS-DRG for these codes is needed, or these codes should be added to the IVL MS-DRGs and to reconsider the root operation definition of atherectomy as fragmentation rather than extirpation. We urge the agency to perform this analysis as soon as practicable.

II.C.4.a. Concomitant Left Atrial Appendage Closure and Cardiac Ablation MS-DRG

In this proposed rule, CMS addresses a request to create a new MS-DRG to better accommodate the costs of concomitant left atrial appendage closure and cardiac ablation for atrial fibrillation. CMS analysis of the request led the agency to propose creation of a new MS-DRG for these concomitant procedures. The ICD-10-PCS codes included in the new MS-DRG (317 Concomitant Left Atrial Appendage Closure and Cardiac Ablation) were expanded to nine left atrial appendage closure codes and 27 cardiac ablation codes. The College would suggest adding ICD-10-PCS code 02583ZF for pulse field ablation, established April 1, 2024, to the included procedure codes for the new MS-DRG. Claims analysis showed that the new MS-DRG would not meet the criteria to create either a two-way or three-way severity split of the MS-DRG.

The College appreciates 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. 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 supports the creation of MS-DRG 317 Concomitant Left Atrial Appendage Closure and Cardiac Ablation with the addition of ICD-10 PCS code 02583ZF for pulse field ablation. 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.

II.C.4.c. Endovascular Cardiac Valve Procedures (TAVR/SAVR)

In this proposed rule, CMS addresses a request to delete the MS-DRGs 266-267 which currently house the transcatheter aortic valve replacement (TAVR) procedures and assign them to the MS-DRGs 216-221, which currently house the surgical aortic valve replacement (SAVR) procedures. The contention of the requestor (the manufacturer of the SAPIEN™ family of transcatheter heart valves) is that these procedures are not profitable to hospitals which leads to factors beyond clinical appropriateness driving treatment decisions. The requestor suggests that having financial neutrality between TAVR and SAVR by being in the same MS-DRGs would relieve any disincentive to perform the TAVR procedures and hence produce more appropriate treatment decisions.

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CMS analysis found that there was too great a difference in cost and length of stay to warrant combining the procedures into a single set of MS-DRGs. Further, the agency notes that following the requestors logic that the TAVR procedures are disincentivized due to MS-DRG placement and hence facility payment, then their proposal may have the opposite effect and simply swap one disincentivized treatment for another. The agency noted that procedural approach should be based on individualized risk-benefit assessment.

The ACC firmly believes that safe, effective, life-saving procedures such as TAVR should be reimbursed at a rate that makes them efficacious for hospitals to perform. However, given the analysis provided by the agency the requested MS-DRG modification may not be the best path to this end. The College urges CMS to devise a supplemental payment mechanism to appropriately facilitate performance of procedures with higher supply costs.

II.C.12.c.1. Social Determinants of Health (SDOH) – Inadequate Housing/Housing Instability

In this proposed rule CMS analyzed mathematical data on the impact of resource use for the subset of ICD-10-CM Z codes dealing with inadequate housing and housing instability. Analysis found that patients with these secondary diagnoses require greater hospital resources. As such, CMS proposes to change the severity level designation of these diagnosis codes from Non-Complicating Conditions (Non-CCs) to Complicating Conditions (CCs).

The specific diagnoses proposed to be changed include:

- Z59.10 – Inadequate housing, unspecified
- Z59.11 – Inadequate housing, environmental temperature
- Z59.12 – Inadequate housing, utilities
- Z59.19 – Other inadequate housing
- Z59.811 – Housing instability, housed, with risk of homelessness
- Z59.812 – Housing instability, housed, homelessness in past 12 months
- Z59.819 – Housing instability, housed unspecified

The ACC supports changing the severity level designation for these diagnosis codes from Non-CC to CC and applauds CMS for recognizing the additional resources required to treat patients with these secondary diagnoses.

II.E.7. Proposed Change to the Method for Determining Whether a Technology Would be Within its 2-to3-Year Newness Period when Considering Eligibility for New Technology Add-on Payments

In the FY2024 IPPS Rule CMS reduced the window of time in which a technology applying for New Technology Add-on Payment (NTAP) could be eligible for a third year of such coverage from what was 3 months down to a single month. The ACC and other stakeholders shared concerns regarding this policy in our comments on the FY2024 proposed rule. In this FY2025 proposed rule CMS proposes extending this window to seven months.

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The College supports any extension of NTAP coverage that allows for greater diffusion of new technology and cost data collection and hence supports this proposal. However, the College also reiterates its belief that NTAP policy should be adjusted so that all devices which receive approval are granted a full three years of NTAP regardless of when FDA approval is achieved.

V.F.2. Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consoidated Appropriations Act, 2023 (CAA, 2023)

CMS proposes an increase of 200 residency positions available to teaching hospitals. This change was directed by Congress in the Consolidated Appropriations Act of 2023. Per that law, at least 100 of those positions are reserved for psychiatry and psychiatry subspecialty programs. Hospitals will apply for new positions by March 31, 2025 and CMS must notify hospitals of its decisions by January 31, 2026 for increases effective July 1, 2026. The ACC supports efforts to bolster the physician workforce. As these positions are awarded, attention must be given to multi-disciplinary management of chronic diseases, such as cardiovascular disease, that cross multiple medical specialties. By 2030, more than 40 percent of American adults are expected to have some form of cardiovascular disease. Given this alarming statistic, funding for multispecialty management of chronic, noncommunicable diseases should "rise to the top." At the same time, the important roles played by primary care physicians, endocrinologists, cardiologists, and others must be recognized.

X.A. 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 proposed TEAM demonstration project is a significant step in testing mandatory focused episode of care models in the inpatient and hospital outpatient settings. For the progression of this value-based care transition, it will be vital to move from the voluntary basis to a mandatory to better understand the impact on the various types of hospitals throughout this country. We agree on the need to continue the momentum built from the Bundled Payment for Care Improvement Advanced (BPCI-A) and the Comprehensive Care for Joint Replacement (CJR) programs. The College is encouraged by the agency's learnings from the existing models and projects. However, our primary areas of concern are:

- 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.
- To meet the desired health equity goals, hospitals lacking administrative resources to analyze the raw CMS data and implement significant changes in a timely fashion will be at a disadvantage.
- Timely and actionable data from CMS must be provided to all TEAM participants along with step-by-step plans 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.

As currently proposed, the ACC cannot support the finalization and implementation of TEAM without significant changes and mitigation of potential unintended consequences for hospitals, clinicians, supporting health care providers and ultimately patients.

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TEAM Participation
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 after the years of the national emergency pandemic, others are struggling to survive and provide care to their communities. In the past 2 years, there have been numerous hospitals closed and hospital employees laid off. If the agency finalizes this proposal, 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.

The College is encouraged by the availability of the 3 Tracks for the hospital participants. We agree with the goal to allow all participants to select Track 1 with no downside risk in the first performance year. The requirement to transition into Track 2 and Track 3 accepting various levels of risk beginning in the second performance year should be contingent on the availability and accessibility of their usable data to anticipate and estimate the impacts of this project on their patients and care planning and pathways.

Proposed Episodes
The College agrees with the sentiment to continue the history of including CABG in the TEAM demonstration project. In addition to the CMS led programs, the CABG procedure has been included in several commercial payers and state Medicaid plan episode of care and value-based projects and arrangements. For purposes of care improvement and research, CABG can provide a more consistent schedule of events compared to other cardiovascular conditions like atrial fibrillation or congestive heart failure.

For the consideration of percutaneous coronary intervention (PCI) for inclusion into TEAM, the College agrees the procedure would be more difficult to implement based on its variation in care including acute and non-acute settings as well as the number of performed outside of the hospital settings. While the College recommends the use of optimal medication therapy for patients with stable coronary artery disease, it is difficult to conclude the underlying condition and rationale for the PCI basis on claims data alone. The ACC National Cardiovascular Data Registry (NCDR©) is taking significant steps in collecting relevant clinical data through its CathPCI Registry™ to better understand the key factors for proceeding to this intervention.

Episode Length
The proposed episode length of 30-days post-discharge appears to be appropriate since the majority of post-event spend including hospital readmissions and post-care inpatient stays occurs within those first 30 days as referenced in the proposed rule. Additionally, several cardiovascular BPCI-A participants experienced significant expenditure shifts in its 90-day episode when two procedures appeared inside the window. Numerous patients had an acute and non-acute percutaneous coronary intervention (PCI) which entered them into the 90-day episode of care then required a transcatheter aortic valve implantation (TAVI) procedure inside the episode resulting in substantially increasing the cost of episode. After consultation with CMS, the College appreciates the agency's change to isolate these procedures from a single episode.

Monitoring and Beneficiary Protection
The College appreciates the agency's proposals to monitor and maintain beneficiary protections including beneficiary choice and notification, access to care, quality of care and delayed care. These will be vital for establishing the success of the TEAM project outside of potential cost savings and care improvements. We

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would like to highlight an additional area of potential concern related to the CABG episode.

As you are likely aware, more and more hospitals and health systems are employing physicians including surgeons and cardiologists as well as developing arrangements with specific care teams. These employment arrangements along with their CABG clinical pathway could open the opportunity for hospitals to exclude external cardiologists and ignore any previous patient-physician relationships until the end of the 30-day episode. Additionally, the hospital could satisfy the requirement to refer the patient to primary care post-discharge without alerting the current cardiologist.

While the patient does have the choice to visit any Medicare physician including their current cardiologist, the hospital could provide at the time of discharge pre-scheduled follow-up visits with the performing surgeon and the employed cardiovascular group as well as access to 24-hour telehealth services for the next 30 days. Such an offering would make any patient second-guess visiting or even returning to their previous physicians. The ACC implores CMS to consider and attempt to mitigate this unintended consequence.

Proposed Quality Measures

As proposed, the TEAM project will include the following measures:

- Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356)
- CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135)
- Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618)

The College greatly appreciates that CMS is utilizing 3 quality measures which are currently collected and evaluated in the Hospital Inpatient Quality Reporting Program. It is important to not increase the administrative burden on hospitals, clinicians, and staffs when possible.

As the agency considers new quality measures, the ACC strongly encourages CMS to explore quality measures collected through the Society of Thoracic Surgeons (STS) National Database™. The registry includes data on nearly 10 million procedures from more than 4,300 surgeons, including 95% of adult cardiac surgery procedures. Adding measures from this registry can inflate the assessment of care quality. Finally, there is strong evidence that use of cardiac rehabilitation post-CABG may reduce long-term mortality as well as improve longitudinal cardiovascular prevention & wellness. As a result, the College would like the agency to consider the inclusion of the quality measure: Cardiac Rehabilitation Patient Referral from an Outpatient Setting to incentivize the issue of cardiac rehabilitation for these patients.

Referral to Primary Care Services

To assist Medicare's goal of 100 percent of traditional Medicare beneficiaries to be in an accountable care arrangement, the proposal would require 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 the accountable care goal, Medicare is prioritizing the post-procedure continuity of care. The ACC agrees with the overall intent to bolster primary care for these patients; however, we question the viability and usefulness of a primary care referral following these intensive

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specialty-focused procedures and hospitalizations.

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

Social Risk Factor

When assessing TEAM hospitals for Safety Net and Rural status, the College is encouraged by the proposal to incorporate several indices specifically state and national area deprivation index (ADI) indicators, the Medicare Part D LIS indicator, and Dual-eligibility status for Medicare and Medicaid**.** It will be important for CMS to provide an open-door policy for hospitals that might be an outlier in a privileged communities or just outside of the applicable zone and could provide additional information for a risk change.

Proposed Waivers of Medicare Program Requirements

The College is in full support of extending additional telehealth waivers to TEAM participants. As the National Health Emergency showed us, it is vital for the health care system to bring care to the patients when appropriate. Access to telehealth visits can address patient and family concerns prior to becoming a hospital readmission or another adverse event. The ACC continues to collaborate with CMS and the Congress to adopt new rules to provide telehealth access for all Medicare beneficiaries.

Health Equity

Like CMS and the Administration, ACC remains committed to advancing health equity and expanding our efforts to support diversity, equity and inclusion in cardiovascular care. The College greatly appreciates the health equity component of TEAM but would emphasize the significant need for patients in these underserved communities and their hospitals to be provided enough resources to participate in the TEAM project but also succeed. CMS must also provide timely and useful historical data on their hospital costs and utilization data.

During the initial phases of BPCI and BPCI-A, CMS gave its participants data which required dedicated staff and consultants to process and make usable for clinicians and their practice staffs. Such equivalent workloads should not be forced on these hospitals particularly the impacted safety net and rural hospitals. The College strongly urges CMS to develop data report one-pagers for the various types of hospital staff and not require dedicated workers to decipher the previous reports which negatively impact hospitals in these underserved communities.

Health Equity Plans and Reporting

The ACC supports the voluntary development of health equity plans for the TEAM participants. These plans aim to identify and address local health disparities and promote equitable access to care for the needs of the individual hospitals' communities. The College is similarly crafting projects and initiatives to identify and assess areas of inequity within the clinical practice of cardiology and accessibility of high-quality cardiovascular care. Also, the ACC favors the initiative to collect Health Related Social Needs Data from the TEAM participants along with the Hospital Inpatient Quality Reporting Program. With that said, as more federal, state, local, and other regulations regarding the collection of social needs data are implemented, clinicians and staff are experiencing data collection fatigue and anxiety especially when they lack resources and

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directions to assist their patients with those needs like housing and food instabilities.

Decarbonization and Resilience Initiative
The ACC supports the voluntary Decarbonization and Resilience Initiative within the TEAM model to help hospitals in addressing the threats to health brought about by carbon emissions and accessing hospitals' role in these emissions. As cardiovascular health is threatened by climate change, the ACC sees the importance of stakeholders across the healthcare industry working to lessen these impacts. Providing participating hospitals with benchmark data is an important first step in helping hospitals to evaluate emissions and energy efficiencies. CMS' technical assistance to enhance organizational sustainability and transition to lower GHG emission care delivery methods will also be of value to hospitals choosing to participate. The voluntary nature of this initiative will allow for the self-identification of hospitals who recognize they are ready to lead in these transitions while protecting un-ready hospitals from financial or administrative burden they cannot sustain.

Medicare Promoting Interoperability Program

IX.F. Proposal to Change the Scoring Methodology Beginning with the EHR Reporting Period in CY 2025

For the Electronic Health Record (EHR) reporting period in CY 2025 and subsequent years, CMS proposes to increase the minimum scoring threshold from 60 points to 80 points. CMS states that 81.5% of eligible hospitals and CAHs that reported to the Medicare Promoting Interoperability (PI) program exceeded a score of 80 points in CY 2022. While the ACC appreciates the continued need to incentivize adoption of evolving industry standards and increased data exchange, the College is concerned that increasing the threshold by 20 points with little to no time for preparation could lead to increased failure rates and decreased compliance. There have been several changes to the PI program, including new measure creation since CY 2022 reporting, which requires continued adjustment by providers and CMS has not released data on scoring for these periods. Additionally, in the past as CMS considers changes to the MIPS and other programs, CMS has provided fair warning and time for adjustment. **Considering these factors, the ACC asks that CMS delay implementation of an increase in the minimum scoring threshold until CY 2026 and subsequent years, providing sufficient time for the nearly 40% of hospitals and CAHs that would not have met the increased threshold time to adjust and meet the updated requirements.**

IX.F.10. Request for Information Regarding Public Health Reporting and Data Exchange

As CMS notes, the COVID-19 public health emergency (PHE) highlighted the interdependencies of public health and healthcare, and the importance of timely, integrated, and interoperable data exchange across the health ecosystem to protect the health and safety of patients, populations, and the broader public. Access to timely, correct information was essential to health professionals as they worked tirelessly to help patients and save lives, especially early in the COVID-19 PHE. However, the importance of public health reporting and data exchange is seen beyond PHEs as the continued advancement of reporting across different agencies, jurisdictions, and states is essential to the public health infrastructure. The ACC thanks CMS for coordinating with agencies such as the Centers for Disease Control (CDC) and engaging stakeholders to seek information on continuing to improve electronic data exchange.

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Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

Currently, the Medicare PI program requires eligible hospitals and CAHs to report their level of "active engagement," which requires attestation of reporting production data or in the process of validation. CMS notes this does not allow them to assess eligible hospitals and CAHs on the comprehensiveness, quality, or timeliness of the data they provide to PHAs. As CMS examines alternatives to the "active engagement" approach, they seek comments on requiring reporting of measures using numerators/denominators and adding measures to include additional system-specific requirements.

While the College understands the need to collect more comprehensive data, including quality and timelines of data reported to PHAs, it is important for CMS to consider the scope of and difficulties that still exists when reporting to agencies. Without established universal standards for reporting to PHAs, the burden for reporting an unknown number of detailed measures could unfairly burden eligible hospitals and CAHs, overwhelming already overworked and burned-out staff. There are limitations that still exist in using singular data sets to meet all requirement needs and creating the number of measures needed to meet the needs of PHAs to sufficiently monitor health across the country would erase any progress CMS has made in the "meaningful measures" initiative. It is essential that CMS work to balance the need for specificity with the burden of reporting and need for standardization.

Instead, ONC should work with the CDC, PHAs, and other stakeholders to identify the scope of system specific measure requirements and determine what would be needed to complete bi-directional clinical data exchange and clearly report these findings. This includes, as will be detailed further below, the creation of a certification program for public health technologies used by PHAs to ensure they have the capabilities required to meet the needs for public health reporting. Outlining these findings and considerations in future rulemaking, such as additional requests for information, would help inform all stakeholders on the scope, benefits, and limitations of an evolving public health reporting program and provide additional informed feedback.

Questions for Goal #3, Increasing Bi-Directional Exchange with Public Health Agencies

The ACC strongly supports HHS' key goal of transitioning to, and use of, more modern, flexible approaches and networks that support data exchange between and across public health and healthcare to modernize the public health information infrastructure. This work should include a multitude of changes to program requirements and continued coordination between HHS, CMS, CDC, ONC and PHAs. One of these areas, as the CDC's Advisory Committee to the Director (ACD) and ONC's Health Information Technology Advisory Committee (HITAC) have recommended, would be the establishment of a certification criteria for public health technologies used by PHAs and implement a coordinated, phased approach to incentivize and eventually require their adoption. **The ACC supports these recommendations and encourages the development of these solutions to help enable bi-directional exchange with PHAs.** Just as ONC and CMS have coordinated to establish certification criteria for Certified Electronic Health Record Technologies (CEHRT), payer requirements, and application programming interface requirements, the development public health technology certification requirements that align with the standards promulgated by the CEHRT, Promoting Interoperability, and Information Blocking requirements would greatly improve bi-directional exchange and help improve the quality, timeliness, and completeness of public health reporting.

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As CMS notes, the HITAC recommended "that ONC establish certification criteria for technologies used by public health, focused on the certification of interoperability functions such as the exchange, access and use (inclusive of response to/acknowledgement) of (as appropriate) both correctly and not-correctly formatted/complete messages that are efficient (do not require "special effort") and effective (provides a common floor that addresses the relevant needs of the public health mission)." It stated, "the goal of certification criteria for public health technologies is to create a common floor to support the exchange of data inclusive of all providers and public health inclusive of the methods by which data are primarily electronically exchanged by Public Health Authorities."

In addition to creating certification requirements, agencies like the CDC and PHAs should consider methodologies to improve interoperability, including participating in the Trusted Exchange Framework and Common Agreement (TEFCA) to establish that common floor HITAC speaks of. The ACC understands TEFCA, still in its infancy, is not the panacea for all interoperability difficulties, and additional enhancements to the program, such as required standards use like FHIR and additional allowed Exchanged Purposes, are needed. **However, the College believes the establishment of a universal governance, policy, and technical floor for nationwide data exchange can only help improve PHA bi-directional exchange and CMS should continue to promote TEFCA's development and use in public health reporting and bi-directional exchange.**

Finally, CMS asks whether they should introduce a similar measure to the newly created "Enabling Exchange Under TEFCA" measure to allow providers to receive credit for the HIE objective by exchanging public health data through participation in TEFCA. While the ACC has supported efforts for CMS to incentivize participation in TEFCA and other programs so long as they are optional measures that afford providers choices that apply to their specialty, the College is concerned about the increased burdens associated with additional measure development. The College once again cautions CMS from creating too many measures in the name of specific use cases and while working to improve data exchange and interoperability, unintentionally exacerbate burnout and administrative burdens providers face every day.

IX.C.6.b. Proposal to Remove Clinical Episode-Based Payment Measures and Substitution of MSPB Hospital

CMS is proposing to remove two cardiovascular-related episode-based payment measures beginning with the 2026 Payment determination: Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction (AMI) (CBE #2431) (AMI Payment), which assesses hospital risk-standardized payment associated with a 30-day episode-of-care for acute myocardial infarction; and Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure (HF) (CBE #2436) (HF Payment), which assesses the hospital risk-standardized payment associated with a 30-day episode-of-care for heart failure for Medicare FFS patients. These would be replaced with the Medicare Spending Per Beneficiary Hospital measure (MSPB Hospital measure) in the Hospital VBP Program. The MSPB Hospital measure has been intermittently included in the Hospital IQR Program's measure set and was recently updated in the Hospital VBP Program. CMS believes that this is a more broadly applicable measure, which includes the ability to evaluate hospitals' efficiency relative to the national median. While the MSPB Hospital measure lacks the same granularity as the condition-specific measures, CMS has noted that performance on these two measures has decreased since FY 2019.

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CMS initially paired these payment measures with corresponding mortality or complication measures, enabling a comprehensive assessment of care value for specific conditions. The intent was for these payment measures to be used alongside existing quality measures, such as CMS's 30-day risk-standardized all-cause mortality measures for conditions like AMI, HF, and pneumonia, as well as the 90-day risk-standardized complication measure for THA/TKA. **However, without these payment measures, aligning quality measures with the MSPB Hospital measure for these conditions becomes not only challenging, but also less meaningful. It is essential to directly link cost measures with clinical quality measures to help stakeholders assess whether reducing costs leads to improved patient outcomes.** One recent study found that in many cases, MSPB was not linked to the quality of care, indicating a lack of outcome accountability among Medicare-funded facilities[1]. Furthermore, worse outcomes were found to be associated with increased spending for some metrics.

AMI and HF are conditions that often require care coordination across multiple providers and settings, including hospitals, primary care providers, specialists, and post-acute care facilities. In a bundled payment model, these single payments are made to cover all services related to the episode of care, encouraging providers to work together to deliver high-quality, cost-effective care. Therefore, payment measures like those for AMI and HF are better suited for facilities with bundled payment models that encompass all entities involved in an episode of care. While the MSPB Hospital measure likewise is intended to account for and encourage coordination of care, it remains to be seen how payments will be affected by a change to the MSPB-only measure. Some hospitals may be better equipped or organized to handle these types of arrangements, thus placing other hospitals at a disadvantage and subsequently accounting for payment differences.

For HF and AMI episodes, two prior studies from the same authors found that higher payments for 30-day episodes were associated with either lower (HF) or slightly lower (AMI) patient-level 30-day mortality, even after adjusting for patient characteristics and comorbidities[2,3]. Hospitals achieving better outcomes may have higher costs due to factors like greater experience in HF or AMI care, or better resources for patient management. These studies also highlight that hospitals with higher payments differ significantly from others, often having better cardiac service capabilities and higher cardiac patient volumes. However, the relationship between higher payments and better outcomes is not fully explained by specific procedures or post-acute care services. While higher payment hospitals may use specialist services more often and focus more on transitions of care, these factors do not entirely explain the observed outcomes.

Heart failure patients tend to carry the burden of the condition over a longer period, so it may be questionable if the MSPB Hospital measure is a suitable substitute. A longer period, perhaps 12 months, would be more appropriate for the chronic nature of this disease. In addition, there is not a "typical" heart failure patient considering that many patients have chronic heart failure. Hospitalization occurs for an acute incidence of the disease, so these should include only certain types of heart failure patients experiencing an acute condition. On the other hand, a consideration for AMI patients is that these patients also tend to be clinically complex, commonly requiring the coordination of care between two or more hospitals for the acute admission. These transfer scenarios may be less important in other disease processes, but require CMS' consideration in terms of payment policies.

CMS previously adopted measure updates to the MSPB Hospital measure (CBE #2158) in the Hospital VBP Program beginning with the FY 2028 program year. These changes included new trigger episodes to expand

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conditions that may be included in the measure, a new variable to indicate if there was a 30-day stay prior to the episode window, and a revision of the calculation from the sum to the mean of observed over expected costs. The measure changes were reviewed by a consensus-based entity (CBE) and received endorsement during the 2020 endorsement cycle and were implemented in the 2023 IQR. According to the Hospital VBP Program's requirements, measures must be publicly reported for one year in the Hospital IQR Program before the start of the performance period in the Hospital VBP Program.

The College recognizes that the MSPB measure may provide hospitals with a less burdensome way to measure resource use. However, one caveat is that the MSPB measure does not inform performance by condition, whereby hospitals may be interested in seeing certain care patterns. In addition, while the MSPB measure is potentially actionable, there is the concern of a potential inverse relationship with outcomes and under-adjustment for social risk factors and medical complexity. Vulnerable groups such as dual-eligible and minority patient populations may drive performance differences in MSPB among hospitals. CMS must ensure that the MSPB measure alone can stand as a reliable and valid measure of efficiency and cost reduction for all hospitals under the VBP program. CMS states that there are quality measures that tie directly to MSPB on Hospital Compare, but for certain stakeholders (i.e., beneficiaries, administrators, the public), it may be a challenge to determine which measures would apply, and whether lower utilization leads to improved outcomes. Finally, it would be beneficial to have reports that can be filtered to show specific areas of spending, as this would enhance buy-in and understanding among individual clinicians. We also encourage the continued provision of detailed reports to providers concerning their efficiency as it pertains to this measure.

Hospitals may reduce inpatient and post-acute care expenditures to cut costs, which could compromise patient care. This risk applies whether a specific 30-day episode measure or the MSPB measure is used. **Overall, CMS should weigh the approach to use the MSPB Hospital measure, as it may not identify specific areas for improvement within individual episodes and may overlook non-Medicare costs (e.g., private insurance or out-of-pocket expenses). It also might not fully consider patient risk factors, and the loss of this data could hinder hospitals' ability to develop and implement cost reduction initiatives effectively.**

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,

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