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September 17, 2021

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

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Submitted via www.regulations.gov

Dear Administrator Brooks-LaSure:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule on the revisions to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payments Systems for calendar year (CY) 2021, published on August 4, 2021. The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

In addition to other aspects, key areas on which the ACC focuses its comments include:

I. Ambulatory Surgery Center Services
II. Inpatient Only List
III. Ambulatory Payment Classification (APC) Assignments

IV. New Technology APC Assignments
V. New Device Transitional Pass-Through Applications
VI. Percutaneous Coronary Intervention-related Services in ASCs
VII. Cardiac Rehabilitation Virtual Direct Supervision
VIII. Advancing to Digital Quality Measurement Request for Information
IX. Closing the Health Equity Gap in CMS Hospital Quality Programs

I. Ambulatory Surgery Center (ASC) Services

Last year, in CY 2021 rulemaking, CMS proposed both to continue the general standard criteria for ASC procedures to add services for CY 2021 (separately paid under OPPS, not be expected to pose a significant safety risk when performed in an ASC, and do not typically require active medical monitoring at midnight following the procedure under standard medical practice), and also proposed two alternatives that could modify the approach for adding procedures to the CPL that is informed by new perspectives. First, the proposed rule explained CMS' belief that significant advancements in medical practice, surgical techniques, medical technology, and other factors have allowed certain ASCs to safely perform procedures that were once too complex, including those involving major blood vessels and other general exclusion criteria. Then CMS looked beyond the difficulties of the public health emergency (PHE), indicating that in the future it would be increasingly important to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible. Because the pandemic forced many ASCs to close, thereby decreasing Medicare beneficiary access to care in that setting, CMS believed allowing greater flexibility for physicians and patients to choose ASCs as the site of care, particularly during the pandemic, would help alleviate both access to care concerns for elective procedures and access to emergency care concerns grew for hospital outpatient departments. Finally, CMS indicated it sought to continue promoting site neutrality, where possible, between the hospital outpatient department and ASC settings, and expanding the CPL to include as many procedures that can be performed in the HOPD as reasonably possible will advance that goal, while allowing physicians to continue playing an important role by exercising their clinical judgment when making site-of-service determinations.

This year, CMS proposes to restore the ASC CPL criteria which had been in place prior to 2021 and proposes to remove 258 of the 267 procedures added to the ASC CPL last year. The Agency also proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. This nomination process would formally add procedures by March 1 for consideration in the following rulemaking cycle. CMS proposes to then evaluate the nominated procedures and allow for public comment in the proposed rule. CMS would have the option to then finalize proposed procedures and or defer to a later rulemaking cycle.

As care continues to evolve it will remain important that physicians have the ability to select a site of service that offers the appropriate level of acuity. **The ACC believes the public nomination proposal CMS describes would best allow this change to advance in a methodical and transparent manner.** This allows the field a greater opportunity to adapt to the changes in standards and vision CMS describes by considering services through the guidance parameters and questions CMS proposes.

Additionally, as more procedures are covered in this setting, the College recommends that CMS consider how to measure and maintain the quality and safety of patient care provided in the ASC setting. **At a minimum, CMS should continue to ensure that services for high-risk patients are performed in the most appropriate setting as defined by clinical guidelines.** The ACC is a strong proponent of participation in a national data registry to allow benchmarking, risk adjustment and facilitates outcomes analysis of local data and should be required.

II. Inpatient Only List (IPO)

Historically, CMS has maintained a list of services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery and, therefore, the service would not be paid by Medicare under the OPPS. In last year's rulemaking cycle, CMS proposed to eliminate the IPO over the next three years, beginning with the removal of 266 musculoskeletal services in CY 2021. For this rulemaking cycle, CMS now proposes to stop the phased elimination of the IPO list and to restore the 298 codes back to the IPO list beginning in CY 2022. Additionally, CMS proposes to exempt these procedures for two years (rather than indefinitely as finalized in the CY 2021 rulemaking cycle) from the two-midnight medical review activities.

The **ACC thanks CMS for halting the phased elimination of the IPO list.** The College believes with more time, the Agency will be able to carefully determine, with a greater measure of certainty, which procedures can be offered to stakeholders in terms of OPPS payment rates, mitigation of new documentation burdens to justify the selected site of service, care quality, and beneficiary impact.

The ACC believes this was a strategic move forward, as the removal of procedures from the IPO list could have been seen as decision point to provide services in the outpatient setting that would not otherwise be considered appropriate for that level of care. The ACC encourages CMS to continue gathering stakeholder feedback on how it should evaluate services for inclusion or exclusion. A transparent evaluation process with public comment period would be a welcome process change.

III. Ambulatory Payment Classification (APC) Assignments

A. Cardiac Computed Tomography

The College remains concerned about payment stability for relatively low volume cardiac imaging services in the OPPS. Cardiac computed tomography (CT) (Code 75572-75574/APC 5571) has generally faced declining or unsteady payment levels in recent years. While the 2022 proposed rule maintains the same APC assignments for these services, payments are again slated to be stagnant and reduced in comparison to just a few years ago, when payment in APC 5571 was 45% higher, about $265 in 2017.

The College recognizes that other factors such as hospital cost reporting contribute to inadequate payment amounts in the proposed rule calculations. Use of generic CT and MR cost center reporting systems will chronically underrepresent costs for these services because they fail to account for enhanced clinical staff time and additional medicines used to perform the service. That means that meaningful cost data will never show a geometric mean cost high enough to support APC reassignment based on costs alone. Additionally, since these services have relatively small utilization in comparison to the rest of an assigned APC, they would not meaningfully impact payment rates within an APC even with a higher geometric mean cost. The trend noted above has created a sustainability spiral where payment reductions mean the services are provided at a greater loss every year.

In the case of cardiac CT angiography, imaging acquisition time and resources are significantly different than other services in APC 5571. Before the scan begins, patients are evaluated by a highly trained CT technologist and a nurse who administers IV medications. The patient is monitored for an extended period while these medications take effect. Electrocardiogram leads are attached for gating that allows images to be obtained at the exact moment in the cardiac cycle when the heart is not moving. When the scan is finally complete, the CT technologist executes imaging processing, which takes longer than other single-organ studies. It is only based on the inadequate cost data that these services are placed in APC 5571 with simpler CT, MR, and X-ray services. Additionally, with the growing number of structural heart procedures (TAVR, TMVR, Watchman, etc.) that depend on CTA for procedural planning, CTA may allow clinician judgement to evenly consider stress testing, CCT, or cardiac catheterization in selected patients. CTA is time intensive to both perform and to read, and therefore it should be reimbursed accordingly.

A two-pronged approach could address this shortcoming in the immediate term and collect more accurate data for a durable solution. First, the ACC urges CMS to place cardiac CT codes75572, 75573, and 75574 with more resource intensive and clinically similar services in APC 5572 to stem facilities losses. This request aligns with previous comments and information submitted by medical societies, including a survey of resource costs at institutions that was submitted to CMS earlier this year to bolster such a request and analysis commissioned by a data consultant. This payment is a more accurate estimation of the minimum cost of performing services. The alternative cost data was derived using a sample of centers with considerable systems and personnel expertise on the latest generation CT scanners. Thus, this data still underestimates mean procedural costs across the country. However, it better represents minimum costs than the cost data gathered under existing OPPS methodology. Cardiac CT has similar homogeneity with respect to resource utilization and cost as procedures grouped under APC 5572 to justify the recommended APC reassignment for the 2022 rulemaking period.

Second, CMS should implement changes that better capture the costs to provide cardiac CT. One approach would be to allow facilities to submit charges for cardiac CT using revenue codes that more accurately estimate costs. Current CMS regulation mandates that cardiac CT be lumped into general diagnostic CT revenue codes. These revenue codes do not account for the specialized clinical staff, supplies, or capital equipment necessary to execute cardiac CT. The College believes that allowing cardiac CT services to be billed using cardiology or stress testing revenue codes will assign a more appropriate cost-to-charge ratio to current services and result in a cost estimation that more

accurately reflects the true cost of cardiac CT. Alternatively, CMS could create line item HCPCS codes for supplies, cardiac technologist and cardiac nurse cost reporting to require facilities to make an entry for these resources. With those cost data available in two years, the Agency should then be able to reassess APC assignment based on collected cost data.

B. Cardiac Magnetic Resonance Imaging

As with cardiac CT, the College remains concerned about payment stability for cardiac magnetic resonance (MR) imaging (Code 75557/APC 5523, Code 75559/Code 5524, Code 75561/APC 5572, and Code 75563/APC 5573). CMS has generally faced declining or unsteady payment levels in recent years. While the 2022 proposed rule maintains the same APC assignments for these services, payments are again slated to be reduced for 75561 and 75563.

75563 was previously included in a nuclear medicine APC, 5593, which was appropriate given the clinical and resource homogeneity of cardiovascular magnetic resonance and cardiac nuclear imaging services. MRI exams of static body parts such as the brain or spine with which 75563 is now grouped typically require only a single MRI technologist to perform and can be completed in less time. CMR exams typically take at least twice as long to perform, and stress CMR exams require additional personnel to administer stress agents and monitor the patient. Thousands of images are generated in a typical CMR exam, covering multiple slices, orientations, and temporal phases of dynamic physiological processes such as perfusion, cardiac function, and blood flow, while brain and spine MRI provide static images of structures only. Additionally, CMR requires intensive post-processing to extract quantitative information and generate the CMR report. Until 2017, CPT 75563 was placed in an APC with comparable nuclear medicine services. The ACC recommends that CPT 75563 be moved back to APC 5593.

Before 2017, 75561 was placed in an APC with other MR imaging and angiography services with contrast that better aligned with clinical effort and costs. That APC was dismantled when a number of imaging APCs were restructured for 2017. Under the proposed APC structure for 2022, this code remains in APC 5572, grouped with services that are not clinically similar or similar in resource use. For example, CPT 75561 has little in common with CT of the abdomen or pelvis or MRI of the neck and spine. CPT 75561 is more comparable to services in APC 5573 (Level 3 Imaging with Contrast). ACC recommends that CMS move CPT 75561 to APC 5573.

Costs presented by CMS in addenda materials suggest these two services cost more than the payment rate, though not approaching the two-times rule. The ACC believes that similar to cardiac CT, collected cost data for both of these services significantly underrepresent the true costs because of limitations of reporting within general MR revenue codes. Allowing cardiac MR services to be billed using cardiology or stress testing revenue codes will assign a more appropriate cost-to-charge ratio to current services and result in a cost estimation that more accurately reflects the true cost of cardiac MR. Alternatively, CMS could create line item HCPCS codes for supplies, cardiac technologist and cardiac nurse cost reporting to require facilities to make an entry for these resources. With those cost data available in two years, the Agency should then be able to reassess APC assignment based on collected cost data.

C. Intravascular Lithotripsy (IVL) Procedures

For 2020 and 2021, CMS created eight HCPCS codes to identify peripheral IVL procedures above the knee (C9764-C9767) and below the knee (C9772-C9975). Five of the eight HCPCS codes are assigned to the appropriate APCs, but three above the knee procedures (C9764-C9766) are assigned to APCs that do not appear appropriate based on cost data. Claims data from 2020 show the mean costs of the three procedures range from 165-217% more than the APC payment. Recently the CMS Advisory Panel on Hospital Outpatient Payment (HOP) recommended reassigning C9764 to APC 5193 and C9765-C9766 if cost data are within 10% of payment for atherectomy services in APC 5194. **The ACC agrees with the HOP that these services are misplaced in the current APCs and recommends CMS move C9764 to APC 5193 and C9765-C9766 to APC 5194.**

IV. New Technology APC Assignments

A. Fractional Flow Reserve Computed Tomography (FFRCT)

Fractional flow reserve can be measured using computed tomography to measure coronary artery disease and plan care for patients, possibly avoiding other downstream tests. FFRCT is a new technology using cardiac CT angiography data to calculate blood flow in the coronary arteries. FFRCT is currently calculated using proprietary data analysis executed at a central data processing facility to develop a three-dimensional image of patients' coronary arteries for measurement of fractional flow reserve. In selected patients for whom cardiac CT angiography shows disease, FFRCT provides additional data for physicians to determine whether an individual will benefit from medical therapy or invasive revascularization. International guidelines such as those from the European Society of Cardiology identify coronary CT Angiography (CCTA) with selective use of FFRCT as a preferred pathway.

CMS proposes to keep code 0503T for FFRCT in New Technology APC 1511 for services with costs between $901 and $1,000. The ACC appreciates the logic of CMS' proposal to set rates based on the collected cost data now that it has several hundred single frequency claims upon which to base APC assignment. However, this number continues to be below the $1,100 cost of the test based on invoices for the FFRCT service provided by members.

Similar to cardiac CT and cardiac MR, the ACC believes this discrepancy stems from flaws in the cost reporting methodology and payment calculation system in OPPS. In this instance, with only a few hundred claims, hospitals that have unintentionally underreported costs can easily bring down the geometric mean cost. Additionally, the formula for determining costs based on cost-to-charge ratios is likely to underrepresent costs, which is the reason a service known to have an invoice price of $1,100 can go through the system and come out with a geometric mean cost of $808. The ACC recommends CMS not finalize this proposal, and instead assign 0503T to APC 1513 for services with costs between $1,101 and $1,200, accepting the $1,100 pricing indicated in invoices, such as the one provided separately to the agency.

Looking beyond 2022 rulemaking, the CMS and stakeholders will need to approach cost reporting and payment mechanisms for this service in innovative ways. FFRCT—and likely other services already in use or on the horizon—does not fit well into the cost reporting and payment structures of the OPPS. FFRCT requires a modest use of facility clinical staff. Additional images are not obtained. Supplies are not consumed. Equipment is not further utilized. Instead, complex computer analysis examines already obtained images to derive a new diagnostic report with important clinical insights that clinicians utilize to better guide care for select patients. The cost of the service to the facility is the price they pay to the vendor. It may be acceptable to leave services like this assigned to new technology APCs that approximate the costs of the service price indefinitely. It may be acceptable to create individual APCs for each technology based on demonstrated costs. It may be possible to group similar services that execute additional processing together. Whichever solution is deployed, it should not be the case that facilities lose money each time they provide high quality care. The ACC looks forward to continuing to engage in finding meaningful solutions that can ensure facilities can provide high quality care with innovative technology.

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

V. New Device Transitional Pass-Through Applications

A. AngelMed Guardian TPT

CMS seeks comments on the clinical improvement aspect of Angel Medical Systems application for transitional pass-through payment for its AngelMed Guardian System. This is a proactive diagnostic technology that monitors patients' electrical cardiac activity for changes that may indicate ST-elevated myocardial infarction (STEMI), non-ST-elevated myocardial infarction (NSTEM), or unstable angina. The device utilizes data acquired from an intracardiac lead and machine learning algorithms to alert patients to potential cardiac events.

ACC's understanding of the trial data and the technology is that the trial demonstrated the technology increases detection of cardiac events, decreases presentation of false positive emergency department visits, and decreases the time to presentation for cardiac events. Earlier diagnosis of cardiac events can lead to better outcomes when myocardial tissue is preserved through earlier treatment. An intervention that leads patients to seek cardiac care in a small number of hours rather than a large number of hours appears an important clinical improvement in comparison to relying on symptoms alone.

VI. Percutaneous Coronary Intervention-related Services in ASCs

As CMS moves more surgical services to the ASC setting, CMS should consider whether updates to the ASC payment methodology are needed in order to provide sufficient and sustainable payment. Recognizing the costs of device-intensive procedures in the ASC setting, the ACC encourages CMS to continue to evaluate policies and the appropriateness of payment amounts for services provided in the ASC as additional cardiovascular services are added to the ASC CPL. A specific consideration for these services should be the appropriate incorporation of related services recommended by literature and guidelines as commonly important for successful PCI. Coronary intravascular ultrasound (IVUS) (92978-92979) and fractional flow reserve (FFR) (93571-93752) are each assigned status indicator "N" and are packaged into other services. With payment for ASC services made at a fraction of the OPPS payment rate, the ACC is concerned that packaging these services at the ASC payment rate could create an incentive for operators to forgo these enhancing technologies in some instances. One way to address this regarding PCI would be for CMS to unpackage these services, a solution the ACC recommends.
The College recommends that CMS consider how to measure and maintain the quality and safety of patient care provided in the ASC setting as more procedures are covered in this setting. At a minimum, CMS should continue to ensure that services for high-risk patients are performed in the most appropriate setting as defined by clinical guidelines.

VII. Cardiac Rehabilitation Virtual Direct Supervision

The proposed rule invites comments on utilization of flexibilities granted during the COVID-19 PHE allowing remote direct supervision of cardiac and pulmonary rehabilitation services, and whether these flexibilities should extend beyond the end of the PHE.
In the proposed CY 2021 Hospital Outpatient Prospective Payment regulation, CMS proposed that direct supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services could be met virtually without requiring the physician's physical presence in that location. The rationale provided by CMS explained that this would continue to improve access for patients and reduce burden for providers after the end of the PHE. Virtual presence would be met through audio/video real-time communications technology (excluding audio-only), subject to the clinical judgment of the supervising physician.

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

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

COVID safety protocols have severely limited and continue to limit patient access to pulmonary, cardiac, and intensive cardiac rehabilitation services. The inclusion of direct supervision via virtual

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

The following information addresses comments submitted by other stakeholders following the proposed permanent status for virtual direct supervision. Questions about safety and oversight were raised by some commenters in response to the CMS consideration of virtual direct supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services.
Beneficiaries begin a cardiac, intensive cardiac, or pulmonary rehabilitation program with the development of an individualized treatment plan (ITP) with the patient. This includes an initial assessment and exercise prescription that is reviewed and signed by the medical director.

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

- 1 cardiac arrest per 111,996 patient-hours, 3.4 myocardial infarctions per 293,990 patient-hours, 1 death per 783,972 patient-hours[2]
- 1 event per 49,565 patient-hours of exercise training[3]
- In higher-risk patients with heart failure, there were similar rates of adverse safety events in patients randomized to cardiac rehabilitation, compared to patients randomized to usual care.[4]

CMS previously stated it intends to monitor the use of interactive audio/video real-time communications technology to meet the direct supervision requirement through the PHE. The professional societies believe it will be evident that the quality and safety of pulmonary, cardiac, and intensive cardiac rehabilitation services are not negatively affected and, in fact, access to these services is improved with a virtual option for direct supervision. **The ACC supports CMS finalizing its proposal from 2021 rulemaking to allow "direct supervision" that includes immediate availability through the virtual presence of the supervising physician or practitioner using real-**

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

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

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

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

time, interactive audio/video communications technology without limitation after the PHE for COVID-19.

VIII. Advancing to Digital Quality Measurement Request for Information

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

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

A. ACC Efforts to Create Standardized Quality Measures

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

through this pilot project will allow NCDR, CRISP, and other entities to gain experience and help advance standards that can be implemented at scale to improve efficiency of data collection effort.

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

B. Definition of Digital Quality Measures

CMS proposes defining digital quality measures as "as quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. A dQM includes a calculation that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources."
The ACC appreciates CMS attempting to refine the definition of digital quality measures from the previous definition of "sources of health information that are captured and can be transmitted electronically and via interoperable systems." **However, the newly proposed definition is still too broad to be meaningful.** For example, if a physician manually enters a patient's blood pressure into the appropriate field of the EHR throughout the year, manually abstracts that information and sends it as a quality measure through a digital transfer, it will meet the proposed definition. Likewise, a physician could create an interface whereby blood pressure readings are obtained at home, seamlessly and securely flow into the appropriate field of the EHR through digital transfer, are abstracted and sent as a quality measure. The first example involves analog to digital transfers while the latter is a digital-to-digital measurement system that aligns much more closely to CMS's vision for digital quality measurement, yet both would fit the definition proposed. The proposed definition also encompasses non-traditional data sources such as wearable devices which may fall outside of CMS and other regulatory agencies' purview. While industry partners developing these devices are actively working to create and adhere to standards, a lack of required data standards, such as adherence to FHIR, could complicate data collection processes and threaten to slow down or prevent data exchange. The overall intent and infrastructure of this definition for dQMs should consider potential reliability and validity issues for new or existing measures. **Due to this, the ACC**

recommends CMS revisit the proposed definition and more specifically align the definition with the requirements quality reporting and value-based purchasing programs would need to meet to fulfill regulatory requirements as well as more clearly defining what differentiates digital quality measurement from existing measures and methodologies.

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

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

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

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

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

The ACC supports CMS' intent to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector where appropriate. The move to

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

IX. Closing the Health Equity Gap in CMS Hospital Quality Programs

Like CMS, the ACC is committed to advancing equity in the delivery of healthcare and healthcare quality to reduce disparities in cardiovascular practice. The College appreciates the administration's focus on health equity and CMS' action to evaluate and implement initiatives in reducing disparities, including this RFI for reducing gaps in care. The enormous costs of U.S. healthcare spending on cardiovascular disease and cardiovascular risk warrant further examination of factors outside of patient care that may contribute to disease. The American Heart Association's most recent "Heart Disease and Stroke Statistics - 2021 Update" used data from MEPS (the Medical Expenditure Panel Survey) to illustrate that the annual direct and indirect costs of cardiovascular disease in the United States for 2016-2017 was an estimated $363.4 billion.[5] Overall, a study by the W.K. Kellogg Foundation and Altarum states that disparities account for roughly $93 billion in excess medical care costs and $42 billion in productivity lost per year.[6] It is clear that improved data collection and quality measurement will be instrumental in helping inform and develop policies to curb costs and potentially reimburse higher quality care, especially given anticipated increases due to an aging population and growth.

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

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

The College believes that data collection efforts should go beyond examining race and ethnicity and include a host of other risk factors to better inform clinicians of patient outcomes. The "Heart Disease and Stroke Statistics - 2021 Update" provides a variety of examples of SDOH which impact

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

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

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

B. Limitations of Data Collection

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

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

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

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

C. Future Efforts to Reduce Health Disparities

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

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

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

Conclusion

CMS consideration of the comments in this letter is appreciated. The ACC looks forward to ongoing engagement with CMS to develop policies that support clinicians' ability to focus on delivering high quality care to patients. The ACC acknowledges the tremendous thought and planning CMS is undertaking to improve the healthcare system. Should you or staff need additional information or have clarifying questions, please contact Claudia Vasquez, Associate Director of Medicare Payment & Quality Policy, at cvasquez@acc.org.

Sincerely,

Dipti Itchhaporia, MD, FACC
President