AMERICAN
COLLEGE of
CARDIOLOGY

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202-375-6000
800-253-4636
Fax: 202-375-7000
www.ACC.org

June 24, 2019

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

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals [CMS–1716–P]

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the FY 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) for acute care hospitals and other policies addressed in this proposed rule. The College's comments focus on several changes to medical severity diagnosis related groups (MS-DRGs), one quality measure of note, and several health IT proposals and requests for information.

The ACC is 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 leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, offers cardiovascular accreditation to hospitals and institutions, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

Changes to MS-DRG Classifications

Comprehensive CC/MCC Analysis

For the first time since FY 2008, CMS proposes changes to severity levels based on a comprehensive mathematic analysis. Since that comprehensive analysis was completed for FY 2008, diagnosis codes have been evaluated individually when receiving requests to change the severity level of specific diagnosis codes. Given the transition to ICD-10-CM and the changes that have occurred to diagnosis codes since 2008, CMS again executed a comprehensive analysis.

CMS described its mathematic model as a guide to be used in conjunction with the judgement of clinical advisors as it classified each secondary diagnosis as an MCC, CC, or non-CC. The ACC did not recreate the mathematic model but is sharing clinical perspective on two groups of changes.

Myocardial Infarction Codes as Secondary Diagnosis

Based on modeling and clinical advisor input, CMS proposes to reassign 13 ICD-10-CM diagnosis codes for acute myocardial infarction and subsequent ST elevation myocardial infarction (STEMI) from severity designation MCC to CC. CMS notes, "Patients with a secondary diagnosis of myocardial infarction may require additional diagnostic imaging, monitoring, medications, and additional interventions, thereby consuming resources that are consistent with CC status." **The ACC opposes this proposal and recommends CMS not finalize this change that would take resources away from MI patients.** Patients with a secondary diagnosis of myocardial infarction absolutely consume additional resources. STEMI patients require cardiology consultation, cycling of cardiac enzymes and revascularization. Patients with a suspected STEMI are placed on high risk medications such as heparin drips and Plavix loads which have caused complications such as cerebral hemorrhages and gastrointestinal bleeding. The monitoring required for these patients exponentially increases and diagnostics such as non-invasive imaging, cardiac biomarkers, telemetry monitoring, serial EKGs, symptom log trajectories, IV pain medications, physician consultation and catheterization lab utilization all proportionally increase as well. The reallocation of STEMI to a CC based on algorithm of resource utilization does not align with the clinical experience of cardiologists in the hospital. This change will result in a loss of length of stay days and have a domino effect related to AMI readmission expectations. STEMI patients with co-morbid conditions such as a new diagnosis of CHF or cardiac arrest are at a much greater risk for readmission. Having resources and time in hospital days is vital to optimize care.

Heart Failure as Secondary Diagnosis

While not discussed in the proposed rule, related Table 6P.1.c also indicates that three ICD-10-CM diagnosis codes for congestive heart failure (CHF) are proposed to be reassigned from severity designation CC to Non-CC. **The ACC also recommends CMS not finalize this proposal that would take resources away from heart failure**

patients. A patient with new onset CHF or chronic CHF requires extensive resource utilization to prevent mortality and hospital readmissions. All acute heart failure requires the same resources whether it is systolic, diastolic, combined or right sided. All should be considered CCs, if not MCCs. Chronic CHF patients also require resources such as cardiology consults, diagnostics, medication adjustments, rehabilitation/physical therapy services, and at times, device implantation that elevate the risk of mortality and readmissions. Patients are administered diuretics frequently, require nursing care with I+Os and frequent electrolyte checks and replacements, daily weights, CXRs, and more intense examinations. This requires more resources than a patient without CHF. If not reimbursed appropriately, an unintended consequence may be the condition is not diagnosed and treated correctly. This will lead to inadequately treated heart failure and more heart failure readmissions.

Patients with major cardiac conditions—like STEMI or CHF—are treated on higher acuity floors. At most hospitals, either cardiac care units or cardiac floors take care of these patients because they offer the highest quality care. Telemetry, frequent cardiac biomarkers, nurse rounding, and experience levels all lead to a better patient outcomes. Many "stop gaps" in put in place for which the resource utilization may not be directly attributable. The ACC is concerned this resource utilization may not be correctly captured, confounding the modeling CMS executed. For both the MI codes and the heart failure codes, ACC suggests CMS reassess the proposed changes as written, giving more weight to feedback from clinical experts that MI and heart failure should not be downgraded as secondary diagnoses. CMS should also consider the financial burden placed on hospital systems, the impact to the types and level of services that can be offered to patients, and the ability to meet quality measures.

Peripheral Extracorporeal Membrane Oxygenation (ECMO)

In FY 2019 rulemaking CMS designated two new ICD-10-PCS codes for peripheral ECMO (5A1522G and 5A1522H) as medical procedures and assigned them to MS-DRGs for other underlying conditions. The changes in the MS-DRG assignments for the ICD-10 PCS codes were based, in part, on CMS clinical advisors' assertion that ECMO via central access requires a new thoracotomy or sternotomy in the operating room and is "extremely invasive and carries significant risks for complications" making central ECMO initiation more resource intensive because of the complex surgery required. However, although, central ECMO patients are critically ill, central ECMO is most commonly used when the heart has not recovered enough near the end of a cardiac surgical operation and the patient cannot come off cardiopulmonary bypass. Central ECMO, its cannula placement, and its initiation most commonly occurs in patients who are already in the operating room and their chest is already open. The cardiopulmonary bypass circuit is removed and replaced with an ECMO circuit. After the ECMO circuit is attached and ECMO initiated, it is maintained for days to weeks with the patient in the ICU. Patients who can successfully wean from ECMO support typically remain hospitalized for additional weeks during the resolution of their critical illness. The clinical advisors' assertion that, because the peripheral ECMO procedures were done in

the catheterization laboratory, ICU, or at bedside the risk is different, is incorrect. Although the cannulation method is different, all other risks for the patients are similar.

In contrast, establishment of percutaneous peripheral ECMO can be done in the operating room, the cardiac catheterization lab or in the intensive care unit (ICU). Regardless of where the percutaneous ECMO cannulation procedure is performed, the situation is typically emergent, and often involves a patient so hemodynamically unstable that transfer to an operating room is unsafe. The notion that percutaneous cannulation for ECMO is associated with less sick patients is fallacious and, in fact, may frequently be a marker for quite the opposite, i.e. patients with the highest acuity receiving an emergent procedure bedside.

The ACC and other stakeholders shared these concerns and additional information over the past year. **The College supports CMS's proposal to reassign the codes for peripheral ECMO (5A1522G and 5A1522H) to Pre-MDC MS-DRG 003.** This change recognizes that method of cannulation should not drive assignment. We anticipate additional data in future years will further demonstrate that conclusion.

In addition, stakeholders continued to work on enhanced ICD-10-PCS coding solutions for the March 2019 ICD-10 Coordination and Maintenance Committee meeting. The new codes resulting from that meeting should also be assigned to Pre-MDC MS-DRG 003.

Transcatheter Mitral Valve Repair with Implant

CMS has considered several different MS-DRG assignments for TMVR in recent years since the new technology add-on payment for TMVR expired. In this rulemaking cycle CMS proposes to assign TMVR procedures into redefined MS-DRGs 266 and 267 for "Endovascular Cardiac Valve Replacement and Supplement Procedures" with and without MCC, respectively. CMS summarized in the proposed rule that most TMVR procedures under the current assignment to MS-DRGs 228 and 229 for "Other Cardiothoracic Procedures" with MCC and without MCC, respectively, have lengths of stay and average costs similar to the existing MS-DRGs for "Transcatheter Cardiac Valve Replacement Procedures" and the proposed "Endovascular Cardiac Valve Replacement and Supplement Procedures" as summarized in Table 1 below.

Table 1

MS-DRG	Number of cases	Average length of stay	Average costs
Current MS-DRG 228 (Other Cardiothoracic Procedures with MCC)—All cases	5,583	9.2	$46,613
Current MS-DRG 228—Cases with procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach)	**1,688**	**5.6**	**$49,569**
CurrentMS-DRG 229 (Other Cardiothoracic Procedures without MCC)—All cases	6,593	4.3	$32,322
Current MS-DRG 229—Cases with procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach)	**2,018**	**1.7**	**$38,321**
Current MS-DRG 266 (Transcatheter Cardiac Valve Replacement Procedures with MCC)—All cases	15,079	5.6	$51,402
Current MS-DRG 267 (Transcatheter Cardiac Valve Replacement Procedures without MCC)—All cases	20,845	2.4	$41,891
Proposed MS-DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC)	16,922	5.7	$51,564
Proposed MS-DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC)	22,958	2.4	$41,563

The ACC recommends CMS finalize its proposal to modify the structure of MS-DRGs 266 and 267 and reassign procedure codes describing a transcatheter cardiac valve repair (supplement) procedure to the newly modified MS-DRGs. It will be important to monitor the impact to assess whether changes may be necessary in the future. For example, as additional technologies are developed and deployed these groupings may need further adjustment.

Inpatient Quality Reporting

All Cause Readmission

CMS proposes to remove the Claims-Based Hospital-Wide All-Cause Readmission (#1789) measure beginning July 1, 2023 through June 30, 2024 reporting period for the FY 2026 payment determination. This measure would be replaced with the proposed Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure (#2879) with Claims and Electronic Health Record Data measure. Payment determination would begin with in FY 2026 after 2 years of voluntary reporting of the Hybrid HWR measure beginning July 1, 2021.

Measure #2879 is a re-designed version of #1789 that combines claims and EHR data. ACC has been cautious of this measure in the past out of concern it be incorrectly applied at the clinician level, rather than the hospital-level. **The College continues to oppose clinician-level measurement using #2879.** CMS should also be cautious about the lack of testing on socioeconomic status (SES) due to lack of availability of EHR data from a nationally representative set of hospitals with patients who represent the full spectrum of SES. Timelines will also be tight for hospitals to collect and validate the data. The ACC suggests CMS implement a testing or pilot year to assess reclassification.

Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

Under the proposed rule, CMS would continue to allow new and returning participants attesting to CMS or their state Medicaid agency to report under the Promoting Interoperability program for any continuous 90-day period within the calendar year for 2021. **The ACC thanks CMS for continuing to provide a 90-day reporting period for CY 2021.** By continuing a reporting period of 90 days, CMS provides clinicians with the flexibility to make sure they can successfully report under the program. The ACC encourages CMS to continue to provide a 90-day reporting period beyond CY 2021 to provide necessary program stability while not drastically increasing reporting requirements and increasing associated reporting burdens on providers.

The College appreciates CMS providing needed stability to the Promoting Interoperability reporting requirements for CY 2020 and minimizing the number of changes to the reporting period, measures, scoring and reporting methods. This stability allows providers to focus on improving the quality of care for patients rather than program reporting requirements. The ACC encourages CMS' continued evaluation of reporting requirements for these and other federal programs to see where associated reporting burdens can be further reduced.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

The College appreciates CMS's continued interest in improving EHR usability, including improving efficiency of providers within EHRs. As CMS evaluates methods for improving EHR efficiency, it is important that CMS not increase the burdens placed on providers through additional reporting requirements. Providers have actively sought to work with health IT vendors to improve EHR efficiency through increased usability. However, many providers resort to custom modifications after an EHR system is installed to improve efficiency and usability.

In comments previously submitted to ONC, the ACC recommended ONC account for usability and user-centered design criteria in the certification process, including the capture of user-reported criteria on usability, user-centered design, and EHR system interoperability. Including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. Specific human-computer interface evaluations methods include but are not limited to heuristic techniques, keystroke level models that sum up the time taken to perform tasks in a system, and comparative analysis between similarly commercially available systems.

Additionally, several user-reported criteria that ONC should consider for inclusion in the EHR certification and maintenance process and published comparison reports including Work-after-work (WOW) time per provider (time spent on an EHR following conclusion of the work day); Measurements of time spent logged into an EHR versus the number of patients seen; Ease of displaying user-defined report formats; and Total time extracting and manipulating health information transferred from external data source. Increasing the availability of this data, those measured by ONC and those reported by end users, to clinicians and health IT decision makers would greatly expand the number of variables to be factored into the EHR procurement process and enable group practices and healthcare systems to make better informed decisions. In turn, EHR vendors would be forced to consider the needs of the end-user when developing EHRs, leading to improved products, decreased frustration and burden for clinicians and patients, and increased time for discussions between clinicians and patient. **The ACC supports the implementation of specific usability and user-centered design criteria into the EHR certification process as one specific method for increasing health IT usability.**

RFI on Provider to Patient Exchange Objective

Immediate Access

CMS seeks comment on whether eligible hospitals and CAHs should make patient health information available immediately through the open, standards-based API, no later than one business day after it is available to the eligible hospital or CAH in their CEHRT. While the College appreciates CMS's intent behind the concept of near immediate access to patient health information through an open, standards-based API, CMS must remain cognizant of situations where a patient receives sensitive information, results or diagnosis when they have not had a chance to discuss with their provider and may have a limited ability to interpret the results. Additionally, without the adjacent widespread deployment

of consent management software, immediate access to health information may inadvertently expose sensitive health information a patient does not want shared.

Finally, while automated processes promise to reduce administrative burdens for providing patients access to health information, speeding up reporting, transmission and access to health information in one business day or less will have a direct impact on provider and staff workflows. CMS must consider the expected impact and increased burdens immediate access will have on current and future workflows. **To successfully allow patients more immediate access to health information, CMS must develop appropriate guardrails to ensure patient information is sufficiently protected from unauthorized access or inadvertent exposure, allow providers and their staff enough time to discuss all health information with a patient before the patient gains electronic access to results or diagnosis, and consider the administrative and workflow impacts of such policies.**

Patient Matching

CMS, ONC, the Congress, and numerous studies have indicated accurate patient matching solutions are essential to the goal of achieving true interoperability and the development of automated and seamless data transmissions. Inaccurate, incorrect, or inconsistent patient demographic or identifying information can enter a patient's record at any point during an encounter and it is crucial that patients and providers have confidence in the accuracy and integrity of the health record. Patient matching errors can be costly and dangerous, as a 2012 College of Healthcare Information Management Executives (CHIME) report showed, 1 in 5 hospital chief information officers indicated that patients had been harmed in the previous year due to patient record mismatches[1].

The recently proposed ONC and CMS rules will help to improve patient matching through defined standardized data elements, the creation of a standard version advancement process, requiring real world testing for certified health IT and the mandated use of API technology. **The College thanks CMS and ONC for taking these steps and encourages the continued emphasis of the importance of patient matching solutions as technological advances continue.**

So long as HHS is prohibited from using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual, **CMS and ONC should continue to work to adopt methods that provide patient matching solutions through technological innovation and collaboration with external stakeholders.** As a recent report from the Government Accountability Office (GAO) indicates[2], stakeholders across the country are developing patient matching applications that utilize algorithms to patch records across care settings and organizations. While these

[1] The Pew Charitable Trusts, *Enhanced Patient Matching is Critical to Achieving Full Promise of Digital Health Records*, October 2018. https://www.pewtrusts.org/-/media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf

[2] GAO, *Heath Information Technology: Approaches and Challenges to Electronically Matching Patients' Records Across Providers*, January 2019. https://www.gao.gov/assets/700/696426.pdf

applications show promise, it is important that ONC and CMS work with standards development organizations (SDOs) and health IT vendors to ensure these programs operate with a very high degree of certainty before they are deployed into the care setting. ONC and CMS should work with SDOs and health IT vendors to set an ambitious, yet attainable match rate for all patient matching algorithms to ensure patients are not exposed to undue harm caused in part by matching errors.

In addition to this needed high degree of certainty, it is vital that SDOs and health IT vendors develop patient matching applications in an open and accessible process. Much like the development of health IT standards put forth in these proposed rules, transparency will provide all stakeholders both the ability to provide input in the developmental stages to ensure unique use-cases are properly considered as well as the needed confidence in both the process and the product created. A transparent and open process led by SDOs and health IT vendors will also ensure technological advances are incorporated into patient matching solutions. For example, as biometric authenticators continue to advance at a rapid pace and are widely accepted across industries, SDOs and vendors should account for the proliferation of this technology.

Patient matching solutions will only serve their intended purpose and successfully protect patients from unintended harm if they are trusted by the vendors, health systems and providers that install and utilize them. As ONC and CMS continue to work on patient matching solutions, the ACC encourages a transparent process which incorporates stakeholder feedback throughout development and deployment.

RFI on Integration of Patient-Generated Health Data (PGHD) into EHRs Using CEHRT

The continued creation of additional methods for generating and transmitting patient-generated health data promises to allow patients and providers alike the ability to monitor their health in real-world settings and provide a more complete picture of a patient's health. While patient-generated health data can help provide a more complete picture of a patient's health and generate additional insights, it is important that this data provide useful data in a standardized format. The addition of patient-generated health data in a non-standardized format will contribute to clinical record note bloat and make it harder to providers to find useful clinical information in the EHR. **The College encourages CMS to consider methods to promote technical solutions or approaches for capturing patient-generated health data and incorporating it into CEHRT using standards-based approaches. This includes bonus points for health care providers or incentives under the Promoting Interoperability program for health IT vendors developing devices that generate and transmit patient-generated health data.**

Finally, in the same way CMS began paying for virtual check-ins and remote evaluation of patient images/video in CY 2019 rulemaking, CMS must also be forward-thinking as it considers how best to compensate systems clinicians for the increased time and complexity of incorporating PGHD into patient care. Too often these tools are viewed as

indirect infrastructure costs, when in fact they require direct expenses that can be attributed to an individual patient encounter or time period.

Request for Information (RFI) on Engaging in Activities that Promote the Safety of the EHR

The College is encouraged by CMS' continued interest in promoting activities that promote the safety of the EHR and supports efforts to reduce medical errors directly or indirectly attributable to EHRs. The College believes incentivizing health IT vendors, hospitals, and providers to promote activities that help to reduce errors, such as more in-depth EHR training or standardized implementation guides, is one way to make drastic improvements in EHR safety.

ONC should also use the Conditions and Maintenance of Certification components of the Promoting Interoperability program as additional policy levers to increase EHR safety through improved usability and user-centered design. The inclusion of **functionality-based criteria such as usability and user-centered design into the Promoting Interoperability Conditions and Maintenance of Certification process would have a positive direct impact on the real-world applications of health IT systems and improve EHR safety.** Numerous studies, including research published by the MedStar Health's National Center for Human Factors in Healthcare, have shown medical errors and patient harm is directly attributable to poorly designed EHR systems. Including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. Factoring these components into the initial design will assist in keeping the total cost of ownership for EHR systems down, enabling practices and health systems to more accurately plan for the resources required for EHR system purchase, installation, training and maintenance.

When undergoing real-world testing in clinical settings, it is also important for ONC to consider the inclusion of user-reported criteria. Practitioners can provide unique insights into the real-world applications of EHR and health IT systems and ONC should incorporate this input into the certification process. The inclusion of user-reported data into the real-world testing and certification process for health IT promises to provide additional pressure for continued progress in addressing the concerns of the clinical community. **Usability and interoperability will only improve when clinicians can provide feedback to ONC and Health IT Vendors that will directly contribute to the certification and maintenance of an EHR system.**

Finally, it is important that ONC and developers are transparent regarding real-world testing performed on certified health IT systems. Making real-world testing data available will provide needed context to ensure health IT acquisition personnel make informed decisions when upgrading or purchasing a new system. **ONC should incorporate real-world testing data into any EHR comparison reports and should emphasize development of a marketing strategy and educational resources to increase awareness of and access to such important comparison tools.** Development of

interactive online and application-based resources that allow for side-by-side comparisons and real-time user input and reviews would provide much-needed accessibility and context to the decision-making process.

Conclusion

The ACC appreciates CMS' consideration of comments on the proposed FY 2020 IPPS regulations. If you have any questions or request additional information, please contact James Vavricek at jvavricek@acc.org or 202-375-6421.

Sincerely,

Richard Kovacs, MD, FACC
President