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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 2019 Rates; etc. [CMS-1694-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 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) for acute care hospitals and other policies addressed in this proposed rule.

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.

The College supports overall efforts by CMS to reduce administrative burden, increase transparency, and support the delivery of value-based cardiovascular care to Medicare beneficiaries in this proposed rule. ACC's comments specifically address the following areas:

- Updates to cardiovascular Medical Severity Diagnosis Related Groups (MS-DRGs), specifically those addressing pacemaker insertions and drug-coated balloons in endovascular procedures;
- Changes to New Technology Add-On Payments for FY 2019;
- The de-duplication and streamlining of measures used under the IPPS hospital quality reporting programs, specifically the Hospital Inpatient Quality Reporting Program (IQR), Hospital Value-Based Purchasing Program (VBP), and the Hospital Readmissions Reduction Program (HRRP), including concerns related to the 30-day readmission metric for heart failure patients currently used under the HRRP;
- Policies promoting the reporting of electronic clinical quality measures (eCQMs);
- Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs;
- ACC's response to the Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid- Participating Providers and Suppliers;
- Support of proposals to reduce administrative burden through the proposed Revision of Hospital Inpatient Admission Orders Documentation Requirements under Medicare Part A and proposed Revisions Regarding Physician Certification and Recertification of Claims; and
- Recommendations on proposed requirements for Hospitals to Make Public a List of Their Standard Charges Via the Internet to support greater transparency of health care costs.

Changes to MS-DRG Classifications

Pacemaker Insertions

The ACC appreciates efforts by CMS to update the MS-DRG GROUPER logic to better recognize the resources and complexity of pacemaker device and lead procedures. **The ACC agrees with CMS' clinical assessment that complete pacemaker insertion procedures always be classified under surgical MS-DRGs when reported as a single procedure or as two procedures (insertion of pacemaker device and insertion of leads) on the same claim for the same encounter.**

However, the ACC cautions CMS on designating certain ICD-10 codes describing the removal or revision of a cardiac lead or cardiac rhythm related device as non-O.R. procedures when reported as a single stand-alone code with a principal diagnosis outside of MDC 5. Currently these procedures, when performed on a patient with a principal diagnosis outside of MDC 5 such

as septicemia or severe shock, may be performed either in an O.R. or in an electrophysiology lab (EP lab) depending on the severity of the patient and the facility's standards. Hospitals performing lab-based procedures may be equipped with EP labs that meet O.R. standards so they can essentially operate as either fully functional diagnostic labs or as surgical settings with scrub areas, advanced fluoroscopic imaging and general anesthesia support, which may be necessary in the event of complications or if the patient presents with a critical illness. In this instance, CMS' logic may consider these procedures "non-O.R." and thus less resource intensive than a surgical procedure, yet the actual resource intensity may be reflective of a surgical procedure. Other facilities may not have advanced EP labs and are performing these procedures in a dedicated O.R.

Rather than complicate the proposal with a carve-out that affects a minimal number of procedures, the ACC recommends that CMS not finalize the proposal to assign the following lead and device procedures as non-O.R. procedures when reported as a single stand-alone code with a principal diagnosis outside of MDC 5.

ICD–10–PCS code	Code description
02PA0MZ	Removal of cardiac lead from heart, open approach.
02PA3MZ	Removal of cardiac lead from heart, percutaneous approach.
02PA4MZ	Removal of cardiac lead from heart, percutaneous endoscopic approach.
02WA0MZ	Revision of cardiac lead in heart, open approach.
02WA3MZ	Revision of cardiac lead in heart, percutaneous approach.
02WA4MZ	Revision of cardiac lead in heart, percutaneous endoscopic approach.
0JPT0PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach.
0JPT3PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, percutaneous approach.
0JWT0PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach.
0JWT3PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach.

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Drug-Coated Balloons in Endovascular Procedures

After ending new technology add-on payments for peripheral endovascular drug-coated balloon (DCB) technologies in FY 2018, CMS received a request to reassign all cases that utilize DCBs to MS-DRG 252, the highest severity level for Other Vascular Procedures with MCC. CMS analysis found that DCB cases comprised about 4% of over 71,000 cases in the three MS-DRGs for Other Vascular Procedures (252, 253, and 254). The DCB cases had a similar average length of stay and higher average costs than the average of all cases in the three MS-DRGs. CMS proposes not to reassign the DCB cases to highest-severity MS-DRG 252 because it would result in overpayment for these cases in MS-DRG 254 that have a shorter length of stay.

The ACC understands CMS's proposal to not arbitrarily "promote" cases from MS-DRG 254 and 253 to 252 based on the presented cost and length of stay analysis, but also cautions that some adjustment should be considered to address the increased costs of DCBs. It would be unfortunate to see facilities inappropriately restrict patient access to DCBs based on financial loss.

New Technology Add-on Payments

Cerebral Protection System

Claret Medical, Inc. applied for a new technology add-on payment for its cerebral protection system that captures and removes thrombus and debris during performance of transcatheter aortic valve replacement (TAVR). Clinical studies are beginning to indicate that the rate of major adverse cardiac and cerebrovascular events is numerically lower in patients undergoing TAVR when the embolic protection system was used. **As the only device approved by the FDA for this purpose, the ACC believes the system represents a substantial clinical improvement that warrants new technology add-on payment to mitigate the financial pressures that could limit use for the prevention of strokes.**

Andexanet Alfa

CMS requests comments on the establishment of a new technology add-on payment for Andexanet Alfa, an antidote used to treat patients who are receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Additionally, the ability to rapidly reverse the anticoagulant effect oral Factor Xa inhibitors can allow a medical procedure or surgery to be performed sooner, which may decrease complications and minimize the cost of additional therapies. This could be a life-saving antidote in many instances. **The ACC believes the antidote represents a substantial clinical improvement over currently available options that warrants new technology add-on payment.**

Overall Comments on Proposed Changes to Hospital Inpatient Prospective Payment System Quality Reporting Programs

The ACC applauds CMS' effort to reduce administrative burden and duplication across the hospital inpatient quality reporting programs. Greater alignment across programs will ensure that hospitals spend more time improving quality rather than tracking quality. As CMS undertakes this effort and further administrative simplification, the ACC encourages the Agency to consider the following:

- Continue to strive toward more universal quality markers and scores, eliminating the need for hospitals to track multiple programs, measures, and databases to assess their performance;
- Align standards across clinician and hospital programs where possible, ensuring that everyone in the health care system is striving toward the same evidence-based patient standards of care;
- Prioritize the improvement of risk adjustment methodologies, especially efforts to understand the impact that socioeconomic status may have on cost, mortality, readmissions, and outcomes;

- Address unintended consequences of quality and resource use metrics, eliminating measures that may inadvertently incentivize lesser standards of care; and
- Likewise, CMS should ensure that the removal of measures from certain programs does not disincentivize hospitals from maintaining standards of care and lead to a decrease in patient quality.

In addition to tackling duplication of measures across the quality reporting programs, CMS should also look to potential areas of overlap between these programs and evolving value-based payment programs. Several of these models, by design, incentivize hospitals to provide more efficient, high quality care. As these models become more mainstream, CMS should expand alignment efforts between the quality and cost metrics used under those models and those under the inpatient quality reporting programs.

In response to this proposed rule, the ACC provides comments on proposed updates to measure removal factors, the Hospital Inpatient Quality Reporting Program (IQR), the Hospital Value-Based Purchasing Program (VBP), and the Hospital Readmissions Reduction Program (HRRP).

Proposed New Measure Removal Factors

The ACC supports the proposal to remove measures from the Hospital VBP Program or the Hospital IQR Program where "the costs associated with a measure outweigh the benefit of its continued use in the program[s]." The College supports applying this factor on a case-by-case basis. Measure types are evolving; as new outcome and patient-reported outcome measures are developed, the initial costs of collecting and reporting this data in a standardized format may be costly even though the measures may offer a significant benefit toward advancing patient care. In applying this case-by-case basis, CMS should be transparent so that the public can understand the standards applied to this factor.

In addition, the College strongly supports the proposal to promptly remove a measure from the Hospital IQR Program and now the Hospital VBP Program if the measure's continued use poses specific patient safety concerns. CMS' hospital quality programs are in place to ensure quality care to patients; it would be counterintuitive to maintain a measure that has the opposite effect. CMS must continuously monitor the impact of measures and emerging literature. By doing so, the Agency will be in a better position to remove measures proactively before widespread patient harm occurs rather than after harm has already occurred. The College specifically encourages CMS to consider this policy later in this comment letter in our response to the use of the 30-day all cause readmission metric for heart failure patients in the Hospital Readmissions Reduction Program (HRRP).

Hospital Inpatient Quality Reporting Program (IQR)

While the College supports the overall measure alignment and de-duplication effort, the ACC recommends that CMS consider the impact of removing measures from the IQR pay-for-reporting based program and maintaining them only in the VBP pay-for-performance based program. CMS should ensure that these changes reduce the burden of quality reporting without unintentionally creating inconsistency or misaligned incentives. The Agency should also consider the impact that these proposed changes have on Hospital Compare and seek input from patients and beneficiaries on the metrics that matter most for informed decision making.

Removal of Mortality Outcome Measures

CMS proposes removal of the measures of hospital 30-day, all cause risk standardized mortality rates following acute myocardial infarction (AMI) hospitalization (NQF #0230), heart failure hospitalization (NQF #0229), and coronary artery bypass graft (CABG) surgery (NQF #2558) from the Hospital IQR. **The ACC cautiously supports removal of these measures based on the rationale that removal from the Hospital IQR would reduce the burden of information collection and review for hospitals and eliminate confusion that beneficiaries may have in seeing these measures publicly reported separately for both the Hospital IQR and the Hospital VBP.**

Future Inclusion of a Hospital-Wide Mortality Measure

CMS considers potential future inclusion of a hospital-wide mortality measure in the Hospital IQR program and seeks public input on whether to adopt a Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure or a Hybrid Hospital-Wide, All-Cause, Risk-Standardized Mortality measure based off a combination of claims and EHR data. **The ACC commends CMS for its early exploration into the development and implementation of a hospital-wide mortality measure. While such a measure would achieve the Agency's goals of utilizing broader metrics, the ACC presents several comments for consideration.**

CMS should ensure that the hospital-wide measure is appropriately risk-adjusted to be actionable and fair to all hospitals, especially if it is to replace condition- and procedure-specific measures of mortality. CMS should weigh this consideration both in terms of the utility of the measure to hospitals as well as to beneficiaries and the public who may view this measure on Hospital Compare. The creation of 13 service-line divisions to inform the overall score may provide some of the specificity needed to pinpoint particular areas for improvement.

With regard to the13 service-line divisions, the ACC supports this concept and is pleased to see that CMS proposes to design specific risk-adjustment models for each division. Risk adjustment is key to the accuracy of this measure and distinct adjustment models will help ensure that the most accurate patient mix data will be used to calculate the data driving the overall score. Within the service lines, CMS proposes 8 non-surgical divisions and 5 surgical divisions described as "mutually exclusive;" however, the ACC recommends that CMS carefully examine whether

these service line divisions are indeed mutually exclusive. For cardiovascular care, CMS proposes a non-surgical cardiac service division and a cardiothoracic surgical division based on the diagnoses and procedures assigned to MDC 5 (Diseases & Disorders of the Circulatory System). Depending on the patient case mix and documentation practices of a hospital, the cases falling under each of these divisions may vary. In addition, there are several cardiovascular services, such as TAVR, that may fall under a cardiothoracic surgical division based on the service, yet also require that hospitals provide significant care under what may be classified under a non-surgical cardiac service division. **The ACC recommends that CMS evaluate the potential for overlap across these categories and recommends that CMS perform a pilot run of data based on these divisions prior to implementation of a measure.**

Finally, as CMS considers whether to implement the hospital-wide mortality measure as a claims-based measure or hybrid measure, the ACC recommends that the Agency weighs both the benefits and limitations of each. The ACC sees benefit in the hybrid measure as clinical EHR data has the potential to provide additional insight into the patient population beyond what can be captured through claims data. That being said, the data captured by EHRs vary significantly and currently hybrid measures have only been tested in a limited number of systems. In deciding whether to implement a claims-only or hybrid measure, CMS should determine whether the burden of collecting additional information through the EHR outweighs the benefit of having additional clinical data.

Removal of Coordination of Care Measures

The ACC supports removal of the 30-day all-cause, risk standardized readmission rate measures following AMI hospitalization (NQF #0505), heart failure hospitalization (NQF # 0330), and CABG surgery (NQF #2515) from the IQR based on administrative simplification. However, the ACC requests that CMS go a step further and consider whether these readmission measures are appropriate as part of the HRRP or if they should be eliminated completely across all quality programs.

Specifically, the ACC raises concern with use of the Hospital 30-Day, All-Cause, Risk Standardized Readmission Rate Following Heart Failure Hospitalization measure (NQF #0330) given emerging literature on the potential inverse correlation between reduced readmissions and increased mortality in this patient population. Based on this trend, reporting a lower readmission rate among heart failure patients may not be an appropriate indicator of quality. The College discusses these concerns in more detail below in response to proposed changes to the HRRP.

Hospital Value-Based Purchasing Program

Removal of Condition-Specific Measures

The ACC cautiously supports removal of three condition-specific payment measures from the Efficiency and Cost Reduction domain, including the measures addressing hospital-level, risk standardized payment associated with a 30-day episode-of-care for acute

myocardial infarction (NQF #2431) and heart failure (NQF #2436). Removal of these measures may actually improve the program as in certain cases, higher 30-day episode payments to hospitals for conditions such as heart failure may be associated with lower mortality and potentially better outcomes, contrary to the incentive design of the VBP.[1] As with the proposed changes to the IQR, although removal of these measures reduces the reporting burden to hospitals, CMS should ensure that removal of condition-specific measures does not limit the ability for hospitals to identify specific trends and areas of improvement in their VBP performance.

The ACC is concerned that removal of the condition-specific measures would mean that the entire Efficiency and Cost Reduction Domain of the VBP will be based on the Medicare Spend Per Beneficiary (MSPB) measure. While the ACC strongly opposes use of the MSPB measure for clinician-level performance, the College recognizes that it may provide hospitals with a less burdensome way to measure resource use. That being said, CMS should not replace administrative burden with an inappropriate measure.

As part of the Improving Medicare Post-Acute Care Transformation Act of 2014 ("IMPACT Act"), the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) issued the *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*.[2] The analysis in the report indicated that large differences in MSPB performance were driven by the use of institutional post-acute care, which was significantly under-risk adjusted for vulnerable groups such as high-dual eligible and minority patient populations. This finding may indicate the potential for measure bias which may lead to unintentional penalization of hospitals that serve poor and complex patient populations. If CMS finalizes removal of the condition-specific measures, the Agency must first 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.

Hospital Readmissions Reduction Program

The ACC agrees that reducing hospital readmissions is an effective strategy for lowering healthcare costs and utilization. **However, as stated earlier, based on emerging literature, the ACC strongly urges CMS to consider whether these measures, particularly the Hospital 30-Day, All-Cause, Risk Standardized Readmission Rate Following Heart Failure Hospitalization measure (NQF #0330) should remain as part of any quality program, whether Hospital IQR or HRRP based on their impact on patient outcomes.**

[1] Rishi K. Wadhera, Karen E. Joynt Maddox, et al, *30-Day Episode Payments and Heart Failure Outcomes Among Medicare Beneficiaries*, JACCL Heart Failure, Vol. 6, Iss. 5 (May 2018).
[2] U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, *Report to Congress: Social Risk Factors and Performance Under Medicare's Value Based Purchasing Programs* (2016).

The College is specifically concerned that the 30-day heart failure readmission metric may have a negative impact on overall patient outcomes and unintentionally penalize hospitals in lower socioeconomic communities. According to Fonarow, Konstam, Yancy, et al, "studies have demonstrated that 30-day readmission rates have a poor or even inverse correlation with process-based quality measures and with 30-day risk- standardized mortality rates."[3] In addition, academic centers and safety-net hospitals that care for larger proportions of patients from lower socioeconomic classes have been shown to be at the highest risk of receiving penalties under the HRRP, raising concerns that those facilities caring for the most vulnerable may be those most subject to the unintended consequences of the program.[4]

Furthermore, the College is concerned that readmission rates are promoted as quality measures when in fact, they may be a strict measure of utilization rather than quality of care. The current payment system incentivizes shorter lengths of stay and reduced readmissions for heart failure patients. This may encourage inappropriate care such as delaying readmissions to beyond the 30-day mark, delaying admissions from the emergency room, and holding patients under observation status without an admission.[5] **CMS must ensure that the inpatient payment system combined with the model of the HRRP does not create harm patients by incentivizing the delay or discouragement of medically necessary readmissions.**

Given these concerns, CMS should at least take actions to better understand the impact of the HRRP, specifically the heart failure readmission measure, on patient outcomes. One interim step could be to stratify data on the Hospital 30-Day, All-Cause, Risk Standardized Readmission Rate Following Heart Failure Hospitalization measure by dual-eligible beneficiary status and other socioeconomic and demographic factors. CMS proposed to do this for the pneumonia readmission and mortality measures in FY 2018; the ACC recommends that the Agency to do the same for the heart failure readmission and mortality measures. Having this data could better inform CMS and researchers on whether the HF readmission measure needs to be eliminated or if improved risk adjustment can eliminate the risks to patient quality and unintended penalties to hospitals treating underserved patient populations.

The College acknowledges that current evidence supporting a direct correlation between the HRRP and increased mortality among heart failure patients may be limited. However, it is worth nothing that in recognizing the success of the HRRP, even MedPAC agrees that literature is mixed on whether efforts to reduce avoidable readmissions have also reduced necessary

[3] Gregg C. Fonarow, Marvin A. Konstam, Clyde W. Yancy, *The Hospital Readmission Reduction Program Is Associated With Fewer Readmissions, More Deaths*, Journal of the American College of Cardiology Vol. 70, Iss. 15 (October 2017).
[4] Ambarish Pandey, Harsh Golwala, et al, *Association of 30-Day Readmission Metric for Heart Failure Under the Hospital Readmissions Reduction Program With Quality of Care and Outcomes*, JACC: Heart Failure Vol. 4, No. 12 (2016).
[5] Ankur Gupta, Larry A. Allen, et al, *Association of the Hospital Readmissions Reduction Program Implementation With Readmission and Mortality Outcomes in Heart Failure*, JAMA Cardiology, Vol. 3, No. 1 (January 2018).

readmissions, resulting in higher mortality for heart failure patients.[6] **Rather than wait to see if this trend continues, CMS should take steps now to determine if the heart failure measure and other measures used under the HRRP can be improved to mitigate the risks to hospitals and to patients.**

The ACC welcomes further conversations with CMS to determine solutions for reducing inappropriate readmissions without posing harm to patients. Should CMS determine that measure removal is warranted, the College cautions the Agency against swift implementation of a new heart failure readmissions metric. Instead, the Agency should consider whether it would be more effective to improve policies or implement models through the Center for Medicare & Medicaid Innovation (CMMI) that better incentivize care coordination between the inpatient, outpatient, and post-acute settings to reduce avoidable readmissions.

Electronic Clinical Quality Measures (eCQMs)

The ACC supports the goal of reducing costs and improving reported data quality and encourages CMS to continue to adopt policies that allow for flexible reporting to best reflect patient populations and support internal quality improvement efforts. However, simply reducing the number of required measures may not result in reduced administrative burden for clinicians and staff. Some of the measures, such as the opioid-related adverse event measures, will still require manual abstraction and documentation, adding to the administrative efforts necessary to successfully report. As CMS considers the total administrative burden placed on clinicians by all quality reporting programs, the ACC urges CMS to reduce the operational burden each specific measure places on clinicians and their medical practice staff. CMS must continue to evaluate associated documentation requirements for measures to effectively reduce the administrative burden facing clinicians.

Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

The ACC has long encouraged CMS to refocus the Meaningful Use program on interoperability, usability, and outcomes rather than the process of capturing and reporting data. The ACC has worked with CMS by submitting comments, asking for the reassessment of thresholds for more realistic benchmarks and eliminating the pass-fail approach to allow for achievement on a sliding scale. CMS seeks to remove requirements that hold physicians accountable for actions beyond their control and address the ever-increasing administrative burden's importance and its effect on clinicians. Through Patients over Paperwork, CMS has focused on identifying and reducing these burdens and the ACC appreciates this emphasis.

[6] Medicare Payment and Advisory Commission, *June 2018 Report to Congress: Medicare and the Health Care Delivery System*, Chapter 1 (June 2018).

Along with Patients over Paperwork, the MyHealthEData Initiative is another step in the right direction, working to put patients in control of their health information and striving to make continued improvements on interoperability. Blue Button 2.0 and expected efforts to prevent information blocking are two encouraging initiatives, as well. The ACC applauds the efforts of all HHS agencies in working to increase interoperability. Finally, the ACC appreciates CMS' efforts to simplify and streamline the Meaningful Use and Advancing Care Information (ACI) programs through the Promoting Interoperability (PI) program. **By acknowledging the shortcomings of previous efforts to encourage EHR adoption through prescriptive rulemaking, CMS is making significant strides towards achieving true interoperability.**

While heartened by the steps taken in the proposed rule, the ACC encourages CMS to use the PI program and others to promote the appropriate, purposeful and accurate use of health IT solutions, rather than mandate completion of tasks. There are objectives and measures that aim to promote interoperability, but CMS should use objectives and measures to focus on the exchange of health information, increased usability of EHRs, and the appropriate realignment of clinical workflows to leverage health IT most effectively to achieve the intention of the PI program and improve patient care.

Medicare and Medicaid Promoting Interoperability Programs

Under the proposed rule, CMS would require the use of 2015 Edition Certified Electronic Health Record Technology (CEHRT) for CY 2019 and beyond. Requiring only 2015 edition CEHRT will help to simplify the PI program and eliminate confusion around different objective and measure sets available for reporting. **Most importantly, the required capabilities required in 2015 edition CEHRT, such as application programing interface (API) functionality and US Core Data for Interoperability (USCDI) through common clinical data set (C-CDS), will encourage continued progress on interoperability.** The ACC encourages CMS to continue to educate and provide resources on 2015 CEHRT criteria as clinician's transition from 2014 to 2015 edition CEHRT.

CMS proposes changing the EHR reporting periods for CY 2019 and CY 2020 to any continuous 90-day period within the calendar year for new and returning participants attesting to CMS or their state Medicaid agency. **The ACC supports CMS' proposed 90-day reporting period for CY 2019 and CY 2020.** Reducing the reporting period to 90 days would provide clinicians with the flexibility needed to ensure successful reporting.

Under the PI program, CMS proposes a new performance-based scoring methodology for CY 2019 and beyond. This proposed performance-based methodology would reduce the number of measures required for reporting from 16 to six for CY 2019 and eight for CY 2020. Members of the cardiovascular care team often cite burdensome federal reporting requirements as a significant contributor to an increased administrative burden imposed upon them. **The ACC appreciates the actions taken by CMS in response to the concerns raised by the College and**

others in the medical community regarding this issue by reducing the number of required measures.

However, it is not just the increase in the number of measures required for reporting that has led to this increased administrative burden. Simply reducing the number of measures required for reporting will not lead to a substantial decrease in the reporting burden. CMS must also consider the operational burden the required measures and reporting process places on clinicians and their staff, as well. Extensive documentation requirements necessitate workflow modifications that diverts clinicians from time spent with patients, adding to frustration and burn out among clinicians. **As CMS considers the total administrative burden placed on clinicians by all quality reporting programs, the ACC urges CMS to reduce the operational burden each specific measure places on clinicians and medical practice staff.**

One component of the operational burden unique to the PI program is the usability of EHR systems. Today, the burden placed on clinicians by EHR is largely defined by the approach taken by EHRs to attain the requisite EHR functionality. These include the EHR's structure, page designs, button placement and utilization, the number of required clicks, tools available through the EHR, and alerts imbedded in the EHR. **While CMS should not mandate interface development for systems, CMS should use its role to ensure vendors continue to work alongside clinicians to improve EHR systems usability and workflow to more appropriately align with clinical practice patterns.**

Scoring

For CY 2019 and beyond, CMS proposes allowing partial credit for eligible hospitals and Critical Access Hospitals (CAHs) by scoring the individual measures. Each measure would contribute to the total PI score and any score over 50 would satisfy reporting requirements for meaningful use. CMS states that statutory requirements and HHS priorities mandate reporting across all objectives to earn any score at all. The ACC appreciates CMS taking the necessary steps to eliminate the pass-fail approach under Meaningful Use. **By providing partial credit under a performance-based scoring methodology, CMS would provide flexibility not currently available under Stage 3 and allows a greater chance of successfully meeting reporting requirements.**

This new scoring methodology would apply to "Medicare-only" eligible hospitals and CAHs as well as "dual-eligible" eligible hospitals and CAHs. CMS does not propose applying the scoring methodology to "Medicaid-only" eligible hospitals, but the Agency does propose to give states the options to adopt the performance-based scoring methodology. **While the ACC understands CMS' intent to not develop prescriptive policies forcing states to adopt policies for their Medicaid programs, the ACC encourages CMS to work with states to adopt aligned scoring methodologies.** The proposed changes to the Meaningful Use and ACI programs are intended to further align the programs, reducing the administrative burden for participants. Hospitals and

CAHs in states that do not adopt aligned scoring methodologies will be forced to report under multiple scoring methodologies and continue to suffer under undue administrative burdens.

Objectives and Measures

As previously mentioned, the ACC believes there are PI objectives and measures that aim to promote interoperability; however, the ACC is unsure many of the PI measures will lead towards achievement of that goal. **Instead, CMS should focus the PI program on a limited handful of high value initiatives that aim to increase the usability of EHR systems, promote clinical data standards, and reduce the amount of necessary manual tasks such as patient matching or data abstraction.**

- *E-prescribing:* The ACC has long acknowledged the benefits of e-prescribing and encouraged cardiovascular specialists to adopt this technology. However, this existing measure does not help promote interoperability. Ideally, data would automatically flow to fields that correspond to the medication in question, reducing the burden for reporting and providing patients and clinicians with useful, automated information. Instead, the College urges the Agency to modify the e-prescribing measure to augment the flow of useful, automated information in an EHR.

- *Health Information Exchange:* Current workflows for EHR systems are cumbersome, often hampered with poor system-to-system interoperability capabilities and manual abstraction of important health information. While EHRs currently do an acceptable job of sending summary of care records within a system, it remains difficult to send among different EHR systems. These issues lead to the creation of burdensome workflows to manage inbound documents, ensuring charts contain correct information, are correctly labeled, and are actionable for clinicians. This is a cost prohibitive process that only leads to a decrease in productivity and increase in time. **CMS should ensure that EHR systems allow for the seamless and effortless exchange of health information**

- *Provide Patients Electronic Access to their Health Information:* The ACC appreciates CMS' proposal to eliminate measure requirements that a patient must view, download and transmit information to a third party or access using an API chosen by the patient. The College agrees that CMS should not hold clinicians accountable for actions beyond their control.

Additionally, the ACC is supportive of efforts to utilize APIs to facilitate the transfer of health information through methods and in formats chosen by patients and clinicians. However, it is imperative that CMS and the Office of the National Coordinator (ONC) provide eligible hospitals, CAHs, clinicians and patients with the necessary education, flexibility and protection to ensure these applications does not expose parties to risk and work with all systems. As previously stated by ONC's Principal Deputy National Coordinator, patients have the right to

access their data through whatever application is convenient to them, even if the application is not secure or well-known. ONC and CMS should diligently work with vendors to develop APIs and provide access to applications that interface with all EHR systems with ease and securely allow patients to access their health information.

Exclusions

Under the proposed rule, CMS would remove the exclusion criteria from all retained Stage 3 measures except for those associated with the e-Prescribing objective and Public Health and Clinical Data Exchange objective. **The ACC disagrees and believes that CMS should retain all exclusion criteria for all measures to provide the greatest amount of flexibility possible.**

While hospitals and CAHs will not have to begin reporting until October 1, 2019 at the latest to meet PI requirements, hospitals, CAHs, and vendors will only have months to prepare for prepare for new reporting requirements and measures. Due to this short implementation timeline, it is pivotal that CMS monitor hospital and vendor progress preparing for the new measures and reporting requirements under the new PI methodology. **Should hospitals and vendors appear to be struggling to implement the new program requirements, CMS should offer an exclusion to ensure eligible hospitals and CAHs are not punished for actions beyond their control.**

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid- Participating Providers and Suppliers

The ACC believes safe and effective electronic exchange of information is essential to achieving true interoperability, but it is only one component of it. Today, it is common for clinicians to rely upon multiple systems to access and enter vital patient health information, requiring hundreds of clicks and contributing to the length of each patient encounter and increasing the time necessary to complete a clinical note and provide proper documentation. Many systems can open and share different documents and files, such as a PDF, with relative ease. However, in many cases, it is difficult for clinicians to extract any information from the document. Instead, the burden is placed on clinicians and staff to compile the necessary information through manual transcription or other methods such as third-party software. **Solely having the ability to transfer medically necessary information to another facility does not constitute true interoperability. Instead, interoperability must include the seamless transmission and receipt of data using consensus methods and standards that allow for effortless extraction, interpretation, and manipulation of data.**

As CMS considers using health and safety standards to further advance electronic exchange of information, the Agency must address the underlying issues preventing interoperability. **The ACC urges CMS to ensure clinicians can seamlessly transmit and receive data without**

having to log into multiple systems and with a minimum number of clicks. CMS must work to improve EHR workflow by working with clinicians and industry partners to encourage the development of platforms that work to increase efficiency and productivity while continuing to make improvements in the quality of care. Additionally, the College believes that CMS must work with clinicians, industry, standards organizations and other relevant stakeholders to develop consensus standards and methods of data transmission. The development and acceptance of consensus standards and methods of data transmission will reduce the number of systems clinicians must access while caring for a patient. These consensus standards and methods of data transmission will also allow third parties to develop applications that can reduce the cognitive burden required to operate these systems and deliver useful clinical intelligence.

The ACC believes CMS should explore using all means to achieve safe and effective electronic exchange of information. While doing so, CMS must balance the potential impact modifications to existing conditions may have on clinicians and care settings and mitigate unintended negative consequences. It is also important that any revisions to conditions and requirements to improve interoperability apply equally to all relevant care settings to promote interoperability across the spectrum. Finally, before modifying any conditions and requirements, CMS must secure the commitment of industry partners to provide clinicians and hospitals with tools and technology capable of meeting the requirements, including assurances to prevent data blocking, provide necessary data liquidity and portability, and work towards true semantic interoperability.

Proposed Revision of Hospital Inpatient Admission Orders Documentation Requirements under Medicare Part A

The ACC supports the proposal to remove the requirement that written inpatient admission orders be present in the medical record as a specific condition of Medicare Part A payment. The College agrees that other available documentation such as the complete medical record, physician notes, and physician certification statements will be sufficient in most cases to justify an inpatient admission paid under Part A. The College supports this and other efforts by CMS to put patients over paperwork.

Requirements for Hospitals to Make Public a List of Their Standard Charges Via the Internet

The ACC commends CMS for prioritizing the creation of a more transparent health care system that empowers patients and clinicians to make the best care decisions under a value-based payment environment. The College supports the proposal to require hospitals to make public a list of their standard charges on the Internet. However, in doing so, CMS must work with hospitals, payers, and other stakeholders to ensure that any publicly released charge data are accurate and actionable. In addition, any increase in the transparency of cost data must be accompanied by robust measures of quality. Patients must be encouraged to seek care based on cost and quality, not cost alone.

As CMS undertakes this effort, the ACC encourages the Agency to consider how to achieve the goal of cost transparency without decreasing the quality of care and patient outcomes and increasing administrative burden. To better assist with the implementation of this proposal, the College provides the following responses to the questions posed in the proposed rule:

What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?

Requiring hospitals to provide standard chargemaster rates and MS-DRG average costs will increase transparency, but may do little to help patients make more informed decisions. Patients are most interested in understanding their real-time, actual out-of-pocket costs. The challenge of providing these data at the point of care is that out-of-pocket costs may differ based on a complexity of factors including the patient's insurance plan or lack of coverage, the site of service where care is delivered, and other discount and pricing policies. If CMS is to meaningfully implement transparency, data releases should be done in a way that is consumer-focused; patients should not be required piece together information in order to understand the cost of their care.

The ACC encourages CMS to use initiatives such as MyHealthEData to work with stakeholders to develop systems that can combine charge information, health plan information, and other key data in a standardized format to calculate and better predict out-of-pocket costs for patients.

Should health care providers be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? What can be done to better inform patients of these obligations? Should health care providers play any role in helping to inform patients of what their out-of- pocket obligations will be?

The ACC supports conversations between patients and clinicians on the cost of care as part of shared decision-making. However, while ideal for clinicians and health care providers to inform patients on their out-of-pocket costs for a service before furnishing that service, this may be difficult to do based on the complexity of factors described above. While CMS should encourage that clinicians and heath care providers discuss out-of-pocket costs with patients, it should not be required at the expense of providing timely care. The development of real-time pricing tools and data sources may eventually support greater discussions of cost at the point of care; until then, CMS must ensure that clinicians focus on the care of the patient. As with patients, CMS should not assume that clinicians can easily navigate the complex health pricing system.

In addition to increasing transparency around the cost of care, CMS must work with health plans, benefit managers, states, hospitals, and other stakeholders to increase information around discount programs and other financial support so clinicians and healthcare providers can make this available to patients. The same stakeholders must also be transparent in providing clinicians

and health care providers with information on utilization management policies such as prior authorization requirements that may impact a patient's ability to receive appropriate care.

If CMS does eventually require clinicians and health care providers to inform patients on their out-of-pocket costs, quality metrics and policies should be in place to recognize clinicians and providers for engaging in shared decision making discussions involving the cost of care. In addition, CMS should ensure that an increase in these discussions drive improved patient care rather than an unintended decrease in quality and outcomes. Improvements in measure stratification and socioeconomic and demographic data collection may support the ability for CMS to identify those patient populations where cost is a significant barrier to health. CMS must monitor performance on process and outcome measures; greater knowledge of out-of-pocket costs should empower patients, not drive avoidance of care based on cost.

Should we require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers? What corresponding regulatory changes would be necessary?

As stated above, CMS should only require clinicians and health care providers to provide patients with information on what Medicare pays for a particular service if this information is accurate and actionable. CMS should not expect clinicians and health care providers to produce this information themselves. To relieve the administrative burden this requirement may place on clinicians and health care providers, the ACC expects that CMS would work with Medicare Administrative Contractors (MACs) and others to provide this information in a standardized format that can then be communicated to the patient.

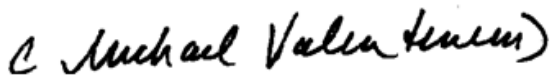
Proposed Revisions Regarding Physician Certification and Recertification of Claims

The ACC supports CMS' proposal to eliminate the need to identify the precise location of the medical rationale for certification or recertification of service(s). Current requirements under § 424.11(c) require that physician statements certifying or recertifying the medical necessity of services need not restate the rationale for the service(s) if supporting information is available elsewhere in the medical records provided; however, the statement must indicate the location within the records where this information is found. CMS has recognized that the location requirement has caused certain claims to be unnecessarily denied; the ACC is pleased that the Agency is taking action to remove this outdated and burdensome requirement in this proposed rule.

Conclusion

The ACC appreciates CMS' consideration of the comments provided in response to the FY 2019 IPPS proposed rule. Should you require additional information or would like to discuss the College's comments in further detail, please contact Christine Perez, Associate Director, Medicare Payment and Quality Policy at (202) 375-6630 or cperez@acc.org.

Sincerely,



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President