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September 11, 2017

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 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs [CMS-1678-P]

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on proposed updates to the Hospital Outpatient Prospective Payment System (OPPS) for 2018.

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.

In considering the impact that CMS' proposals have on patient access to high-quality cardiovascular care in the hospital outpatient setting, the ACC addresses the following subjects in this comment letter:

- The ACC supports reinstatement of the notice of nonenforcement of the direct supervision instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds in CY 2018 and CY 2019;
- The ACC recommends changes to the proposed Imaging Ambulatory Payment Classification (APC) structure for CY 2018 in order to maintain payment stability for cardiovascular imaging services;
- The ACC recommends addition of acute myocardial infarction, percutaneous coronary intervention (AMI-PCI) cases reported by CPT code 92941 to the Inpatient Only List; and
- The ACC provides comments on proposed changes to the Hospital Outpatient Quality Reporting (OQR) Program, addressing measures of fibrinolytic therapy (OP-1 and OP-2) and the incorporation of social risk factor information.

Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

The ACC strongly supports CMS' proposal to reinstate the notice of nonenforcement of the direct supervision instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds in CY 2018 and CY 2019. This proposal is in line with CMS' goals to eliminate regulatory barriers to patient access to care.

CMS should provide public notice of the process and timeline for submitting specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment (HOP Panel) for recommended changes in the supervision level. The ACC specifically supports policies that allow for non-physician advanced practice professionals (e.g., physician assistants, nurse practitioners) to supervise cardiac rehabilitation services. Engagement in a cardiac rehabilitation program can have a positive impact on a patient's quality of life and may reduce hospital readmission and mortality risks. However, the current physician direct supervision requirement makes it difficult to provide access to cardiac rehabilitation where physicians are scarce. The nonenforcement of direct supervision instruction proposed in this rule can help address this barrier in limited areas while a permanent change in the overall supervision policy is developed and implemented.

Imaging APCs

Since 2015, proposed changes to the Imaging APC structure have resulted in substantial payment cuts finalized for cardiac imaging services, particularly echocardiography and magnetic resonance. For CY 2018, CMS proposes modifications to the Imaging APC structure for contrast enhanced imaging services by shifting nine MRI services from APC 5572 to APC 5573, resulting in two-times rule violations and diluted clinical and resource homogeneity. The 2018 proposal results in cuts of up to 27% between 2017 and 2018 for cardiac magnetic resonance with contrast (75561 and 75563). For rest echocardiography with contrast (C8929), the proposed payment of $488 is only $15 more than the proposed payment of the corresponding rest echocardiography without contrast (93306). This difference would be insufficient to cover the supplies and agents used for the contrast procedure. The ACC is concerned that this ongoing payment instability threatens the ability for hospitals to ensure patient access to clinically appropriate imaging modalities.

The ACC, along with the American Society of Echocardiography (ASE) and the Society for Cardiovascular Magnetic Resonance (SCMR), recommend that CMS not implement proposed changes to the Imaging APCs and maintain the CY 2017 structure and payment in CY 2018. Maintaining the status quo for another calendar year will provide stability for cardiac imaging payments and a natural breakpoint between the Level 2 and Level 3 Imaging with Contrast APCs. This will also provide the ACC, ASE, SCMR, and other cardiovascular imaging groups additional time to work with CMS to better understand two years of cost data under the same structure and to develop a more sustainable configuration for cardiac imaging.

Alternate Proposal

Should CMS wish to consider an alternate option, the ACC, ASE, and SCMR would support a realignment of the Level 2 and Level 3 Diagnostic Imaging with Contrast APCs. Moving the ten MRI services described by CPT codes 71551, 73223, 72157, 70543, 70553, 72158, 72156, 71550, 74183, and 72197 to a separate APC creates greater economic similarity within APC grouping, eliminates the two times rule violation, and offers a more natural breakpoint between APC costs of $484.28 and $554.89. Under this proposal, we recommend that CMS move the MRI services listed above from APC 5573 to a new APC. The ACC believes that this proposal would reasonably address the cardiac imaging payment issues created by the CMS proposal and would limit any changes to the Imaging with Contrast APC set, minimizing disruption to other imaging APCs.

Addition to the Inpatient-Only List: AMI-PCI

The ACC and the Society for Cardiovascular Angiography and Interventions (SCAI) recommend that acute myocardial infarction, percutaneous coronary intervention (AMI-PCI) cases reported using CPT code 92941 be classified as "inpatient-only" to prevent AMI-PCI patients from being inappropriately relegated to outpatient/observation status by facilities. While there are numerous codes that describe PCI procedures, there is only one CPT code that is used to report PCI performed emergently to treat AMI patients. All AMI-PCI cases are reported using CPT 92941 (*Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel).* The ACC and SCAI believe it is reasonable that the hospital stay for a typical AMI-PCI patient is expected to be two midnights or longer.

Requirements for the Hospital Outpatient Quality Reporting Program (OQR)

Proposed Removal of OP-1: Median Time to Fibrinolysis Beginning with the CY 2021 Payment Determination

The ACC supports removal of OP-1 from the Hospital OQR Program in CY 2021 and future years. The College agrees with CMS' assessment that the collection of median door to needle time alone does not indicate whether the hospital is meeting recommended guideline of therapy within 30 minutes of emergency department arrival, which is measured by OP-2.

With regard to both OP-1 and OP-2, CMS should consider the value of these measures in assessing the overall quality of care under the Hospital OQR. The 2013 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guideline for the Management of ST-Elevation Myocardial Infarction recommend fibrinolytic therapy as a primary reperfusion strategy when primary PCI is not readily available. With increased catheterization lab availability, the volume of patients receiving thrombolytic as a primary perfusion strategy is small. There may still be some value to measurement in areas such as rural and critical access hospital settings where primary PCI may not be readily available and fibrinolytic remains the standard approach to timely STEMI treatment. In the FY 2016 Hospital Inpatient Prospective Payment System (IPPS) final rule, CMS removed AMI-7, Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival, recognizing that it is infrequently reported by hospitals. CMS should determine whether this also applies to the outpatient setting based on the current guidelines.

Future Electronic Quality Measure (eCQM) Development of OP-2: Fibrinolytic Therapy Received within 30 Minutes of ED Arrival

CMS proposes to develop OP-2 as an eCQM for future years of the Hospital OQR Program, stating that it is the most feasible out of all existing measures. While the ACC appreciates that CMS is dedicating time to the development of eCQMs, the College questions whether there is value in devoting resources to this specific measure. eCQM specification and testing is a resource-intensive process. As stated above, more patients are being treated with PCI than fibrinolytic therapy based on the current clinical guidelines and standards of care. **CMS should consider whether it makes sense to develop OP-2 as an eCQM or to focus on a different measure that may not be as feasible, but may have greater longevity under the Hospital OQR Program.**

Accounting for Social Risk Factors in the Hospital OQR Program

The ACC supports CMS' interest in accounting for social risk factors in the Hospital OQR Program. As CMS undertakes this effort, the Agency should keep several factors in mind. First, CMS should ensure that social risk factors do not outweigh evidence-based measures in the determination of quality care.

Socioeconomic status and social risk factors have a clear impact on patient health and outcomes; however, any quality of care measurement should be primarily based on the medical treatment provided to a patient.

Second, CMS should align any efforts to account social risk factors in the Hospital OQR Program with similar efforts underway in other Medicare payment programs. The ACC is aware of similar discussions as part of the Hospital Value-Based Purchasing Program (VBP) in the inpatient setting as well as the Quality Payment Program (QPP) under Medicare Part B. In order to reduce the potential for duplicative or even conflicting data collection processes and methodologies, CMS should ensure that any policies accounting for social risk factors across the Medicare quality reporting programs are as consistent as possible. As part of this alignment, CMS should also work with measure developers to determine how to best incorporate social risk factors as part of measure development or risk adjustment methodologies.

Third, CMS should continue to consider potential limitations in data collection in accounting for social risk factors. CMS must work with the EHR vendor and clinical data registry communities to ensure that data standards are in place for the collection of socioeconomic data. CMS must also recognize that those communities that treat the most vulnerable populations may be limited in their ability to implement robust EHR systems that can easily integrate collection of this data.

Finally, and most importantly, CMS must consider the impact of socioeconomic data collection on the patient. The collection of socioeconomic data must not discourage Medicare beneficiaries from seeking care. CMS must engage patients, social support networks and clinicians in meaningful education on how the collection of this data is used to improve care and not to influence the treatment that a Medicare beneficiary may receive.

Closing

The ACC appreciates CMS' consideration of the comments provided in this letter. The College encourages CMS to maintain a transparent process for engaging stakeholder feedback through future rulemaking and utilization of the HOP Panel. As CMS makes updates to the OPPS, the College asks that the Agency continue to prioritize policies that provide a stable environment for patient access to high-quality, evidence-based cardiovascular care. Please contact Christine Perez, Associate Director, Medicare Payment & Quality Policy at (202) 375-6630 or at cperez@acc.org should you have any questions or require additional information.

Sincerely,

Mary Norine Walsh, MD, FACC
President