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September 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model [CMS-1695-P]

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the CY 2019 Hospital Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center (ASC) Payment System, 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 ACC is committed to policies that support patient access to high-quality cardiovascular care in the most clinically appropriate setting. In this letter, the College provides comments on the following areas of the proposed rule:

- Support of updates to the ambulatory payment classifications (APCs) for imaging and endovascular procedures, with recommendations;
- Discussion of cost allocation methodologies for reporting data used to calculate annual cost to charge ratios and APC relative weights;
- Discussion of proposals to limit the scope of off-campus provider-based departments (PBDs). Specifically, concerns regarding the proposal to equalize

- payment for clinic visits provided under the OPPS in exempted off-campus PBDs with the Physician Fee Schedule (PFS) rate for office visits;
- Critical issues CMS must evaluate as it considers expanding the Secretary's authority to further limit unnecessary increases in outpatient department utilization;
- Support of the proposal to add 12 diagnostic cardiac catheterization services to the covered ASC procedure list, with recommendations;
- Comments on the Hospital Outpatient Quality Reporting Program;
- 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; and
- ACC's response to the Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

Endovascular Procedures (APCs 5191 through 5194)

The transitional pass-through payment under the OPPS for drug-coated balloons (DCBs) expired December 31, 2017, with stakeholders expressing concern that the current four-level comprehensive APC (C-APC) structure may not provide sufficient payment for cases using these devices. The College appreciates CMS' consideration of two new C-APC proposals in the proposed rule, including a five-level structure and a six-level structure although no changes were proposed. **As the ACC continues to assess the impact of these proposals on the payment for other endovascular procedures within the clinical family, the College encourages CMS to continue its review of data on the use of DCBs and to potentially address APC structure and payment for services using these devices in future years.**

Imaging APCs

The ACC supports CMS' proposal to maintain the existing 2018 Imaging APC assignments for CY 2019, while continuing to monitor payment for all services and to work with stakeholders to identify long-term solutions for payment stability. Over the past several years, CMS has proposed significant changes to the Imaging APC structure, which if finalized, would have threatened payment stability for these services and limited stakeholders' ability to properly assess cost trends and changes over time.

The College continues to remain concerned about payment stability for cardiac magnetic resonance with contrast services, particularly cardiac magnetic resonance imaging (MR) for morphology with dye (CPT Code: 75561/APC 5572). In 2018, CMS' proposed rule would have resulted in an over 20 percent cut to this service between 2017 and 2018. The ACC appreciates that CMS did not finalize its proposal. While the 2019 proposal maintains the same APC classification for 75561, the proposed payment for this service is set to decline by 15 percent from the 2018 payment amount. Such a substantial decrease would threaten the ability of hospitals to maintain the equipment, supplies, and agents used for this service.

The ACC asks that CMS continue to monitor payment for cardiac MR services, specifically CPT code 75561, which has been subject to drastic proposed payment cuts year after year. As part of this request, the College asks that CMS better define the standard used to determine clinical homogeneity for imaging procedures, as recent APC assignments have resulted in a variety of modalities within a category that seem to differ clinically. The ACC welcomes to opportunity to further discuss this with CMS' clinical experts.

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In addition, the ACC asks that CMS study how best to assign "low volume procedures" to an APC. The College acknowledges that the service described by CPT Code 75561 is a low volume procedure, especially relative to other procedures within APC 5572 as well as the other imaging APCs. As a result, it is unlikely to influence the overall payment in any APC it is assigned to. The ACC asks that CMS work with stakeholders to explore a modified APC structure or changes to the current assignment methodology that would support payment stability for low volume services such as cardiac MR.

The College recognizes that there may be other factors such as hospital cost reporting and the changes and delays to CMS' CCR methodology for CT and MR that may be contributing to inadequate payment amounts in the proposed rule calculations. Maintaining the APC structure for another year allows the College and others to further assess the potential drivers behind this variability.

Cost to Charge Ratios

The ACC recognizes that the different cost reporting methods used by hospitals may contribute to the artificially low relative payment weights and payment amounts for MR discussed above, as well as potentially other services. In this proposed rule, CMS' analysis shows that removing cost data based on the "square foot" cost allocation method from the CCR calculation results in a payment increase for nearly all imaging APCs for CY 2019, including APCs housing cardiac computed tomography (CT) and MR services that have been subject to substantial proposed cuts in this proposed rule and prior years' proposed OPPS rules.

The College appreciates the analysis provided in the proposed rule related to the implementation of cost centers and distinct cost to charge ratios (CCRs) for CT and MR finalized in 2014. In the CY 2014 OPPS final rule, CMS finalized a policy to remove claims from providers that report a cost allocation method of "square feet" to calculate the CCRs used to estimate APC costs for CR and MR, based on CMS' analysis that this methodology is imprecise.

The ACC believes that accurate cost reporting is instrumental to the development of valid and appropriate payment amounts under the OPPS. However, the College also acknowledges that for some hospitals, moving to a "direct assignment" or "dollar value" only cost allocation methodology is administratively burdensome. CMS proposes to end the period for hospitals to transition away from the "square feet" cost allocation method and other less accurate methods at the end of CY 2019. Starting in CY 2020, CMS will calculate APC relative payment weights based on cost data from all providers, regardless of the cost allocation method used. **The College recommends that CMS include a detailed analysis of the impact of this transition in the CY 2020 proposed OPPS rule so stakeholders can fully assess its impact on proposed APC payments.**

While the ACC supports the movement toward more accurate cost data collection and payments, the College requests that CMS continue to explore policies that ensure data accuracy and payment stability while minimizing the administrative burden on hospitals. This includes ongoing consideration of what cost allocation methods should be accepted by CMS for payment rate calculations, how to address the availability of sufficient and accurate data for low volume procedures, as well as monitoring the need for unique MR and CT CCRs in the future.

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Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services

Eliminating Payment Differentials

The ACC agrees that managing increases in beneficiary cost-sharing must be a priority for CMS. To address this, CMS has created policies to eliminate payment differentials across settings of care and reduce incentives to provide care in a higher-cost setting. Most recently, through the implementation of the section 603 amendments to section 1833(t) of the Act, CMS has implemented policies to limit the ability of non-grandfathered hospital off-campus departments to receive full payment for services paid under the OPPS.

As CMS moves toward a site-neutral payment system, the ACC presents the following principles that must guide any payment policy changes in this area:

- Changes to Medicare payment should not harm access to care and quality of care, especially for vulnerable patient populations.
- Medicare payments should reflect the resources required to provide patient care in each setting—physician office, hospital outpatient, hospital inpatient. The "correct" payment may be different in different settings.
- Any payment differences across sites should be related to documented differences in the resources needed to ensure patient access and high-quality care. Some limits on payment differentials for the same service provided in different settings may be reasonable.
- Medicare payments for all sites of care should account for costs related to emergency capacity, compliance with regulatory requirements, geographic differences, quality improvement activities and higher need populations.
- Proposals to make significant changes to Medicare's payment systems (e.g., site neutral payment proposals) should be carefully aligned with other rapid changes in healthcare, including the movement to value-based purchasing and alternative payment systems.
- Major changes should be implemented gradually to minimize any negative impacts on patient access and quality.

Payment for Clinic Visits (HCPCS code G0463)

Given what CMS believes is an unnecessary increase in the volume of clinic visits provided in hospital outpatient departments, the Agency proposes to apply a PFS-equivalent payment rate for clinic visits still paid at the full OPPS rate. Under the proposal, HCPCS code G0463 will be paid at the facility PFS rate for a Level 3 visit regardless of whether the service was provided in an excepted non-excepted off-campus outpatient department.

While the ACC supports the rationale behind this proposal, the College recommends that CMS delay implementation of the proposal to pay clinic visits (G0463) provided in off-campus OPDs at the PFS rate until the impact of this reduction can be better understood. The College specifically urges CMS to consider a delay in light of the proposals to reconfigure payment for evaluation and management (E/M) services under the CY 2019 PFS proposed rule that would layer one disruptive change on top of another.

If finalized, the PFS proposed rule would create two single payment amounts; one for new patients at a level that is between the current payments for 99203 and 99204, and a single payment for existing patients that is between the amounts for 99213 and 99214. The PFS proposal also includes additional add-

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on codes for additional time and complexity for primary care and specialty services. Depending on the combination of add-on codes used, the equivalent PFS rate for G0463 may vary. CMS' proposal in the OPPS was based on the CY 2018 PFS and OPPS rules, which crosswalked G0463 to a Level 3 visit under the PFS. CMS should not finalize the proposal to pay the outpatient clinic visit described by G0463 until an equivalent or appropriate payment rate based on the PFS can be determined.

Service Line Restrictions

To limit the expansion of services provided by off-campus provider-based departments (PBDs), CMS proposes to identify 19 clinical families where exempted off-campus PBDs would continue to be paid the full OPPS rate for services falling within these groups. **The ACC supports this approach and agrees that identifying clinical families rather than specific exempted services or setting annual service caps allows CMS to strike a balance between limiting the expansion of off-campus PBDs, while ensuring that hospitals can continue to provide patients with access to new technologies or services within a given service line.** The College specifically appreciates CMS' proposal to recognize cardiac/pulmonary rehabilitation, vascular/endovascular/cardiovascular, and major and minor imaging clinical families under this proposal.

As CMS looks to further limit the expansion of excepted off-campus PBDs, the Agency should continue to monitor the impact of this policy and all proposals related to section 603 on patient access to care. Specifically, the College agrees that CMS should consider whether future exemptions may be needed in the event that these limitations impact patient access to care, particularly in rural areas or areas where hospital closures or clinician shortages have led to limited settings of care.

Recommendations of the Advisory Panel on Hospital Outpatient Payment

At their August 20, 2018 meeting, the HOP Panel discussed CMS' proposals related to controlling unnecessary increases in the volume of outpatient services and provided the following recommendation: *"The Panel recommends that CMS not implement the proposals for reduction in payment for outpatient clinic visits or restrictions to service line expansions. The Panel recommends that CMS study the matter to better understand the reasons for increased utilization of outpatient services."*[1]

The ACC agrees with the recommendations of the Advisory Panel on Hospital Outpatient Payment ("HOP Panel") and strongly encourages CMS to consider the Panel's request for a study on the factors behind increased utilization of outpatient services. The College also recommends that CMS investigate specific questions raised by the HOP Panel such as whether reducing payment in the outpatient clinic setting would have an impact on shared decision making and the availability of other services such as the involvement of chaplains, social workers, and other community support resources.

In addition, as CMS and the Center for Medicare and Medicaid Innovation (CMMI) continue to explore new payment models, the Agency should determine whether restrictions on the volume of outpatient services stifle the ability to create new care delivery models that may lead to long-term improved outcomes and value.

[1] August 20, 2018 Advisory Panel on Hospital Outpatient Payment Recommendations, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.

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Expansion of the Secretary's Statutory Authority to Additional Items and Services That May Represent Unnecessary Increases in Outpatient Department Utilization

The ACC recognizes CMS' interest in managing rising health care spending by limiting unnecessary increases in service volume and shifting care to lower cost settings. While these are reasonable goals, the College urges CMS to ensure that any future proposals do not create additional barriers to patient access to care. The ACC provides the following comments in response to the specific questions posed by CMS in this proposed rule. The College recommends that CMS continue discussions on this topic in a transparent manner with stakeholders as the Agency looks to expand the Secretary's authority on managing the volume of outpatient care.

- *How might Medicare define the terms "unnecessary" and "increase" for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness, and patient demographics?*

CMS should not assume that an "increase" in the volume of covered OPD services automatically means correlates to an increase in "unnecessary" services. As CMS notes, there may be factors such as the severity of a patient's illness, patient demographics, or limited patient access to certain settings of care that may drive increased utilization in the outpatient setting. The clinician's documentation for services ordered should always be the source of determining the necessity of services for a specific patient.

Any method to control unnecessary increases in the volume of covered OPD services should include full consideration of peer reviewed literature, guidelines, and appropriate use criteria (AUC) available for a given service and indication. AUC, in particular, can be an effective tool for CMS in assessing the scenarios where there are gaps in the clinical guidelines, but available evidence indicates that a particular service may be reasonable to do. Organizations such as the ACC develop AUC by convening panels of practicing clinicians to review the latest science, practice trends, best practices, and economic data to provide ratings of whether or not services are appropriate, may be appropriate, or are rarely appropriate for a particular patient population. Since 2005, the ACC has developed over 20 AUC documents for cardiovascular topics such as cardiovascular imaging, diagnostic catheterization, and coronary revascularization.

Finally, CMS should investigate duplicative procedures, such as diagnostic testing performed separately by different providers, as a potential driver of unnecessary services. Medical procedures are commonly duplicated when the original service obtained suboptimal results. This can occur when testing is performed by an improperly trained clinician and/or using incorrectly calibrated equipment. For example, cardiologists often review a patient's clinical notes and echocardiogram images obtained by a primary care provider. In instances of unclear imaging, a cardiologist may be unable to confirm the patient's diagnosis and need to re-order the echocardiogram. While the ACC supports properly trained clinicians performing these services with correctly functioning equipment in any office or setting, CMS and its Medicare Administrative Contractors should research providers and institutions with higher rates of downstream, duplicate services as a source of unnecessary services. The ACC would be interested in discussing this research opportunity with CMS.

- *While we are proposing to pay the PFS payment rate for clinic visits beginning in CY 2019, we also are interested in other methods to control for unnecessary increases in the volume of outpatient services. Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the*

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service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?

CMS should not consider blanket prior authorization as a method for controlling overutilization of services under the OPPS. The ACC is concerned that enforcing prior authorization for services provided to the Medicare fee-for-service population will lead to increased inefficiency and may further contribute to delays in patient care. Furthermore, prior authorization continues to be a top administrative burden and frustration identified by both cardiologists and the medical community as a whole attempting to deliver high quality and effective care. Expanding prior authorization to outpatient services provided under Medicare without addressing current issues with the process would contradict CMS' Patients Over Paperwork initiative and goals to deliver quality patient care.

If CMS is to explore prior authorization as an option, the ACC strongly urges the Agency to consider numerous issues with the process that are currently experienced through Medicare Advantage (MA) and other health plans. Clinicians have been forced to hire significant professional staff dedicated to managing requests and calls with prior authorization vendors, many of which result in the need for peer to peer (ordering physician to vendor-employed physician) discussion which pulls clinicians away from time with other patients. Doctor visits are commonly delayed and/or extended while waiting for authorization decisions leading to multiple hour visits and rescheduled care.

Prior authorization should only be used if CMS can guarantee that it will not create additional burden for clinicians and patients. The ACC has launched the PARTool, a web-based tool that collects data from clinicians to determine overall prior authorization and test substitution trends and the barriers to care created through the prior authorization process. The College welcomes the opportunity to discuss this data with CMS as the Agency explores utilization management options.[2]

While the ACC opposes the broad application of prior authorization, the College acknowledges that there may be a limited scope where prior authorization may be beneficial. For example, CMS may consider applying prior authorization to outliers or those whose ordering rates are not in compliance with clinical guidelines and standards of care. Subjecting a wide range of services to prior authorization, especially when a high rate of these services is eventually approved on a regular basis, creates unnecessary burden for clinicians, their patients, and even payers and prior authorization vendors.

The ACC, along with the American Medical Association and several specialty and state medical associations have developed principles that should apply to any prior authorization or utilization management program. These principles recommend that any program be based on clinical validity, support the continuity of patient care, be transparent and fair, provide timely access to care and administrative efficiency, and provide alternatives and exemptions to those clinicians with appropriate utilization rates.[3]

[2] Hadley Wilson, Robert Shor, *ACC Tackling Prior Authorization*, JACC Vol. 70, Iss. 9 (Aug 2017). Available at: https://doi.org/10.1016/j.jacc.2017.07.727.

[3] American Medical Association, American College of Cardiology, et al. *Prior Authorization and Utilization Management Reform Principles*. Available at: https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Latest%20in%20Cardiology/Advocacy%20and%20Policy/PA%20Reform%20Principles.pdf?la=en.

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- *For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?*

Patient safety and outcomes must be a priority over the cost of care. Shifting services to a lower cost setting should only be done when supported by clinical guidelines and when CMS can ensure that such a shift will not harm the quality of care received by a patient. For example, an older patient may require a diagnostic cardiac catheterization that can be performed in a lower cost setting such as an ambulatory surgical center (ASC). However, due to multiple co-morbidities and documented risk factors, the treating clinician determines that the procedure should be performed in a hospital because of these complex factors that warrant the need for a more specialized facility, more trained personnel support, or a higher risk of complications that may warrant a need to admit that patient. A clinician's medical judgment in selecting the best setting of care for the patient should not be overshadowed by a push to select the lowest cost setting.

CMS should also consider the availability of quality programs and metrics in each setting. The Hospital Outpatient Quality Reporting Program currently contains a robust set of measures, many of which are targeted at measuring the care provided to cardiovascular patients. The ASC Quality Program has a list of 12 measures, none of which are cardiovascular condition or procedure specific. As CMS looks to shift more intensive services from the OPPS setting to the lower cost ASC setting, the Agency should ensure that there are clinically relevant metrics in place to track the quality of care that patients receive in this and other lower cost settings.

- *Several private health plans use utilization management as a cost-containment strategy. How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?*

The College acknowledges that health plans are invested in the use of utilization management as a cost-containment strategy. However, flaws in the current processes used by plans have contributed greater administrative burden to clinicians and increased barriers to care for patients, with many services ultimately approved. As stated earlier, utilization management must be based on clinical validity, support the continuity of patient care, be transparent and fair, provide timely access to care and administrative efficiency, and provide alternatives and exemptions to those clinicians with appropriate utilization rates.[4]

It is important to note that the ACC-developed practice guidelines, AUC, expert consensus documents as well as peer reviewed medical literature are intended to provide recommendations and a potential guide for making clinical treatment decisions for a "typical" patient. In order to make an actual clinical treatment decision, the College instructs our members to weigh the individual patient conditions and factors along with our recommendations. Private health plans too often make absolute coverage decisions based on these recommendations without considering the individual patient's needs. The College stresses the importance that any utilization management policies do not erode the ability for the clinician to exercise his or her reasonable clinical judgment in determining what is most appropriate for the patient.

The ACC supports the use of AUC and evidence-based clinical guidelines and pathways as effective clinical-decision support tools to assist clinicians and hospitals in the reduction of potentially harmful or rarely appropriate services. CMS should incentivize the use of clinical support processes and consultation with clinical guidelines, clinical pathways, and AUC in ways that fit seamlessly into the clinician workflow and patient interaction. Such requirements should not add additional administrative

[4] Ibid.

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burden to clinicians. CMS is currently implementing the AUC program for advanced imaging services in the outpatient setting under the PFS. The ACC encourages the CMS hospital outpatient division to work with others within the Agency, as well as external stakeholders, to determine how the goals of the AUC program can be achieved through existing programs under the PFS and OPPS.

- *How should we account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas? With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?*

CMS should examine the impact that any policy would have on clinicians, hospitals, and patients, particularly in rural areas and health provider shortage areas. The Agency should consider the factors that may be driving increases in OPD utilization in these regions. For example, a sole community hospital may be the only setting in a particular geographic region that has the equipment to perform an advanced diagnostic procedure. In this instance, an increase or higher than expected rate in the OPD setting would be reasonable as patients would not be able to seek the service in the physician office or a lower cost setting. In addition, many of these hospitals in underserved areas may have limited capital to invest in additional staff to facilitate a larger influx of utilization management requests. CMS should consider exceptions or flexible policies that support the ability of these facilities to provide patients with sufficient access to care.

- *What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?*

If implemented improperly, prior authorization and other utilization controls may inadvertently contribute to delays in patient care, additional visits, travel costs and greater cost-sharing rather than less. For example, a lengthy prior authorization approval process could lead to a patient having to schedule another visit or additional intermediate tests or services being performed while approval is pending. CMS must ensure that any methods to control unnecessary increases in the volume of covered OPD services does not interfere with the beneficiary's ability to access appropriate care in a timely manner. As stated earlier, the ACC is collecting data on the impact of the prior authorization process on the delivery of care through the PARTool and would welcome the opportunity to discuss this data with CMS.

- *What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?*

As stated earlier, CMS should consider cases where exceptions may lead to improvements in the quality and value of patient care. CMS should provide flexibility for entities engaged in alternative payment models, particularly those based on shared risk, where increased outpatient utilization may lead to better long-term patient outcomes and potentially greater savings under other Medicare payment programs for the inpatient, post-acute, and home health settings. The ACC agrees with statements made by panelists at the August 2018 HOP Panel meeting voicing concerns that limitations on the volume of outpatient services may stifle the innovation of new care delivery models and recommends that exceptions should be made in these scenarios.

<u>Expansion of ASC Covered Surgical Procedures</u>

The ACC supports the proposed addition of 12 cardiac catheterization procedures (93451-93462) to the list of ASC covered surgical procedures for CY 2019. The College agrees with CMS' clinical assessment that these procedures can be safely performed in an ASC. To further support the ability to perform these procedures in an ASC, the College recommends that CMS also add the following

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procedures to the list of ancillary services covered in the ASC setting when performed with a covered surgical procedure:

HCPCS Code	Descriptor
93463	Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed
93464	Physiologic exercise study (eg, bicycle or arm ergometry) including assessing hemodynamic measurements before and after
93505	Endomyocardial biopsy
93530	Right heart catheterization, for congenital cardiac anomalies
93531	Combined right heart catheterization and retrograde left heart catheterization, for congenital cardiac anomalies
93532	Combined right heart catheterization and transseptal left heart catheterization through intact septum with or without retrograde left heart catheterization, for congenital cardiac anomalies
93533	Combined right heart catheterization and transseptal left heart catheterization through existing septal opening, with or without retrograde left heart catheterization, for congenital cardiac anomalies
93561	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement
93562	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (List separately in addition to code for primary procedure)
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or

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	therapeutic intervention including imaging supervision, interpretation and report; initial vessel
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel

Allowing these cardiac catheterization and concomitant procedures to be performed in an ASC is in line with CMS' goals to expand access to services and encourage the delivery of care in the lowest cost setting. However, merely identifying these services as covered services under the ASC setting does not necessarily mean that it will be economically feasible to do so. Cardiovascular interventions require the use of multiple devices. At around 40 percent of the OPPS payment rate, the ASC payment rate for these procedures may be insufficient to cover the costs of these procedures.

As CMS moves more surgical services to this setting, CMS should consider whether updates to the ASC payment methodology are needed in order to provide sufficient and sustainable payment. The proposed rule makes strides toward better 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 covered services list.

In addition, 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.

Hospital Outpatient Quality Reporting Program (OQR)

The ACC supports continued measurement of the quality of care provided in the hospital outpatient setting. Similar to efforts finalized under the IPPS, CMS proposes to update the OQR measure set to focus on key patient outcomes, while reducing the overall cost and administrative burden of participating in the program. As stated in response to the IPPS proposed rule, the ACC supports the elimination of measures where the cost of reporting the measure outweighs the benefit to the patient. As part of this assessment, CMS must also consider the right balance between reducing the number of measures used in the program, while maintaining a sufficient list of clinically relevant and actionable measures that allow hospitals to identify specific areas for improvement.

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, 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, it is often difficult for clinicians to extract any information from the resulting 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**

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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 promote an environment which ensures 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 collaborating with clinicians and industry partners to encourage the development of platforms that increase efficiency and productivity while improving 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 each 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 all means for achieving 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 essential that any revisions to conditions and requirements for improving 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.**

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

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. 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:

- *How should we define "standard charges" in provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should "standard charges" be defined to mean: average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list, or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of the average contracted rate and the*

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chargemaster, price list, or charge list? Or is the best measure of a provider's or supplier's standard charges its chargemaster, price list, or charge list?

Requiring hospitals to provide standard chargemaster rates and 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.

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

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, discount information, patient assistance programs, 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

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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.

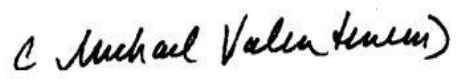
- *Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular services performed by that provider or supplier? If so, what changes would need to be made by providers and suppliers. What burden would be added as a result of such a requirement?*

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.

Conclusion

The ACC appreciates CMS' consideration of the comments provided to this proposed rule. The College looks forward to further engagement on the policies proposed in this rule and future efforts to ensure access to cardiovascular care in the hospital outpatient setting. Should you need additional information or have any questions, please contact Christine Perez, Associate Director, Medicare Payment & Quality Policy, at (202) 375-6630 or at cperez@acc.org.

Sincerely,



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