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Submitted via www.regulations.gov

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

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule on the revisions to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payments Systems for calendar year (CY) 2021, published on August 3, 2020. The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit *acc.org.*

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

- Ambulatory Surgery Center Services
- Inpatient Only List
- Imaging Ambulatory Payment Classification (APC) Assignments

- Fractional Flow Reserve Computed Tomography (FFRCT)
- Prior Authorization
- Separate Payment & Medical Devices
- Physician-owned Hospital Expansion

Ambulatory Surgery Center Services

In CY 2019 rulemaking to revise the definition of "surgery" to include "surgery-like" procedures with CPT codes outside the CPT surgical range that are clinically similar to procedures in the CPT surgical range, do not pose a significant safety risk, are not expected to require an overnight stay, and are separately paid under the OPPS. In CY 2020 rulemaking, CMS conducted a review of codes not on the ASC Covered Procedures List (CPL) and added three percutaneous coronary intervention procedures to the CPL. This proposal built on the decision to add a number of diagnostic coronary catheterization services to the CPL under the revised definition in CY 2019 rulemaking. CMS proposes to build on these proposals in the cardiovascular space and similar proposals in other clinical areas by finding new ways to allow more services to be performed in the ASC.

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

Public Nomination Option

The first alternative CMS proposes to expand the CPL is a public nomination process. Stakeholders already make suggestions to CMS regarding the addition of services, and it the Agency notes it could be beneficial to adopt a streamlined and transparent nomination process. Nominations would be made by March 1 for the following calendar year. This process could begin for CY 2022.

To broaden the pool of services that could be potentially be performed in an ASC, CMS would eliminate existing general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5) such that nominated procedures would not have to meet those criteria. Criteria proposed for removal include procedures that (1) Generally result in extensive blood loss; (2) Require major or prolonged invasion of body cavities; (3) Directly involve major blood vessels; (4) Are generally emergent or life threatening in nature; and (5) Commonly require systemic thrombolytic therapy. Parameters—not requirements—to guide submission and consideration of submissions are also proposed.

Systematic Expansion Proposal

Under the second proposal CMS offers that would allow for more immediate changes, CMS would again eliminate existing general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5) such that nominated procedures would not have to meet those criteria. CMS explains this change would allow physicians practicing in the ASC setting, who have the greatest familiarity and insight into the needs of individual beneficiaries, to use their complex medical judgment to determine whether they can safely perform a procedure in the ASC, given the entirety of the circumstances, including the clinical profile of the patient, the surgical back-up available at the ASC, and the ability to safely and timely respond to unexpected complications. With those exclusion criteria eliminated, CMS proposes that roughly 270 procedures would meet the newly loosened criteria and be added to the CPL for CY 2021. The procedures identified under this alternative proposal were found to be surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, that have not been designated as requiring inpatient care under 419.22(n) as of December 31, 2020, that can be reported without using a CPT unlisted surgical procedure code, and are not otherwise excluded under 42 CFR 411.15. CMS seeks comment on this approach and the removal of any services proposed for addition to the CPL that stakeholders feel would require care after midnight.

ACC Feedback on CPL Changes

The ACC agrees that technological and clinical advances continue to allow procedures to move to lower acuity sites of service, and previously offering qualified support to add a number of diagnostic cardiac catheterization and percutaneous coronary intervention procedures to the CPL. The ACC also agrees access to care is paramount and quickly shifting in uncertain times. Allowing more services in ASCs may ease burdens on patients seeking care. Though the ACC cautions that ASCs are not necessarily located in areas that face care shortages (rural or underserved urban areas) and urges CMS and providers to consider implications of these policy changes on care equity.

As care continues to evolve it will remain important that physicians have the ability to select a site of service that offers the appropriate level of acuity. **The ACC believes the public nomination proposal CMS describes would best allow this change to advance in a methodical and transparent manner.** This allows the field a greater opportunity to adapt to the changes in standards and vision CMS describes by considering services through the guidance parameters and questions CMS proposes. These guiding questions would provide a helpful baseline rubric to begin the possible addition of services to the CPL. The ACC could envision exceptions or counterexamples to these parameters, so they may warrant refining in future years. As the rule describes, stakeholders already present information and recommendations to the Agency. A nomination framework of this nature will make those changes more transparent and allow for

Should CMS move forward with an immediate expansion of the services included in Table 40, **the ACC recommends removal of codes C9602-C9608 from any final list for CY 2021.** Percutaneous coronary intervention using atherectomy, through a bypass graft, and of a chronic total occlusion are services that require a higher level of acuity. As when they were posited for performance in the ASC last year, they should remain the facility setting at this time while additional experience in the ASC setting grows. Angioplasty and stenting have only been on the CPL for nine months, making it premature to put more complex interventions on the CPL. Over time, after review of registry data and in discussion with subspecialty societies, the ACC can see the possibility of these procedures taking similar steps toward ASC, with certain protocols.

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.**

Additionally, participation in a national data registry allows benchmarking, risk adjustment and facilitates outcomes analysis of local data and should be required.

CMS indicates a desire to push for site neutrality between hospital outpatient and ASC settings. The ACC recognizes the opportunities to reduce costs through site-neutral payment policies but warns against rushing to the lowest possible payment. CMS proposes to give significant deference to beneficiaries' preferences and physicians' clinical knowledge and experience when it loosens policies that could shift services from the hospital outpatient setting to the ASC setting and from the inpatient setting to the outpatient setting. Comparable deference must also be given to patients and physicians when they choose NOT to move to a lower acuity care setting. The ACC has previously devoted significant consideration to meaningful principles that should guide site-neutral payment policies and shares them here for consideration.

- Changes to Medicare payment should prioritize patient access, quality and value of care.
- Approaches to remove unnecessary and/or unexpected cost to patients and the health care system, including equity across outpatient ambulatory settings, should be discussed.
- Significant changes to address payment disparities between sites of service must be phased in over time to safeguard the stability of the health care system.
- Proposals must consider the financial impact of changes on the stability of the health care system, particularly those providing care to underserved populations.
- Site of service payment policies must be aligned with programmatic and systemic changes to avoid unnecessary complexity and promote the successful transition to a value-based payment system.
- Any payment differences across sites should be related to documented differences in the resources needed to ensure patient access and high-quality care.
- Medicare payments for all sites of care should account for costs related to emergency capacity, compliance with regulatory requirements, geographic differences, quality improvement activities, higher need populations, or other factors relevant to a site of service.

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. Recognizing the costs of device-intensive procedures in the ASC setting, the ACC encourages CMS to continue to evaluate policies and the appropriateness of payment amounts for services provided in the ASC as additional cardiovascular services are added to

the ASC CPL. A specific consideration for these services should be the appropriate incorporation of related services recommended by literature and guidelines as commonly important for successful PCI.[1, 2, 3] Coronary intravascular ultrasound (IVUS) (92978-92979) and fractional flow reserve (FFR) (93571-93752) are both assigned status indicator "N" and are packaged into other services. With payment for ASC services made at a fraction of the OPPS payment rate, the ACC is concerned that packaging these services at the ASC payment rate could create an incentive for operators to forgo these enhancing technologies in some instances. One way to address this regarding PCI would be for CMS to unpackage these services, a solution the ACC recommends.[4, 5]

Inpatient Only (IPO) List

Since CY 2000, CMS has maintained a list of services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery and, therefore, the service would not be paid by Medicare under the OPPS. In this proposed rule, CMS proposes to eliminate the IPO over the next three years, beginning with the removal of 266 musculoskeletal services in CY 2021.

The Agency notes that despite the existence of the IPO, it has always been the expectation that the surgeon and the hospital will assess the risk of a procedure or service to the individual

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[1] This study demonstrated that IVUS-guided DES implantation significantly improved clinical outcome in all-comers, particularly for patients who had an IVUS-defined optimal procedure compared to angiography guidance.
Zhang J, Gao X, Kan J, Ge Z, Han L, Lu S, Tian N, Lin S, Lu Q, Wu X, Li Q, Liu Z, Chen Y, Qian X, Juan Wang Chai D, Chen C, Li X, Gogas BD, Pan T, Shan S, Ye F, Chen SL, Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers: The ULTIMATE trial, Journal of the American College of Cardiology (2018), doi: https://doi.org/10.1016/j.jacc.2018.09.013.

[2] Among patients requiring long coronary stent implantation, the use of IVUS-guided everolimus-eluting stent implantation, compared with angiography-guided stent implantation, resulted in a significantly lower rate of the composite of major adverse cardiac events at 1 year. These differences were primarily due to lower risk of target lesion revascularization.
Hong S, Kim B, MD; Shin, D, et al. Effect of Intravascular Ultrasound–Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation The IVUS-XPL Randomized Clinical Trial. The Journal of the American Medical Association. 2015;314(20):2155-2163. doi:10.1001/jama.2015.15454. Published online November 10, 2015. Corrected on February 2, 2016.

[3] Among patients with complex coronary artery lesion, IVUS-guided PCI was associated with the lower long-term risk of cardiac death and adverse cardiac events compared with angiography-guided PCI. Use of IVUS should be actively considered for complex PCI.
Choi K, Song Y, Lee J, et al. Impact of Intravascular Ultrasound-Guided Percutaneous Coronary Intervention on Long-Term Clinical Outcomes in Patients Undergoing Complex Procedures. JACC: Cardiovascular Interventions. Volume 12, Issue 7, 8 April 2019, Pages 607-620.

[4] Functional revascularization for lesions with visually severe stenosis is clinically safe and associated with fewer stents use. This study suggests that extending the use of FFR to more severe coronary lesions may be reasonable.
Zhang Y, Li J, Flammer A, et al. Long-term outcomes after fractional flow reserve reserve-guided percutaneous coronary intervention in patients with severe coronary stenosis. J Geriatr Cardiol 2019; 16: 329–337. doi:10.11909/j.issn.1671-5411.2019.04.001

[5] The authors conclude that on-site CT-FFR based on a ML algorithm can provide good diagnostic performance for detecting hemodynamically significant CAD, suggesting the high value of coronary CTA for selected patients in clinical practice.
Kurata A, Fukuyama N, Hirai K, et al. On-Site Computed Tomography-Derived Fractional Flow Reserve Using a Machine-Learning Algorithm - Clinical Effectiveness in a Retrospective Multicenter Cohort. Circ J.2019 Jun 25;83(7):1563-1571. doi: 10.1253/circj.CJ-19-0163. Epub 2019 Jun 8.

patient, taking site of service into account, and will act in that patient's best interests. As such, CMS has reconsidered various stakeholder comments requesting elimination of the IPO list and reevaluated the need to restrict payment for certain procedures in the hospital outpatient setting. CMS no longer believes there is a need for the IPO list in order to identify services that require inpatient care. Instead, CMS now feels that the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. CMS believes this change will ensure maximum availability of services to beneficiaries in the outpatient setting, noting the evolving nature in of the practice of medicine, physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list.

Some stakeholders have supported maintaining the IPO list and consider it an important tool to indicate which services are appropriate to furnish in the outpatient setting and to ensure that Medicare beneficiaries receive quality care. Without the IPO list, patient safety and care quality could decline, and the potential for surgical complications could increase if specific procedures are performed in the outpatient setting for the Medicare population. The IPO list also streamlines some administrative burdens, as services included on the IPO list are an exception to the 2-midnight rule and as such are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

The ACC agrees that technological and clinical advances increasingly continue to allow procedures to move to lower acuity sites of service. Physicians' clinical knowledge and judgment can be relied upon to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences. When executed under general coverage rules requiring that any procedure be reasonable and necessary, payment should be made pursuant to applicable payment policies. However, it is unknown exactly how smoothly such a transition can be made in such a short period of time. While the ACC appreciates the intent to allow clinicians greater autonomy in making these decisions, **the ACC urges CMS to delay proposed removal of the IPO list until a greater measure of certainty can be offered to stakeholders in terms of OPPS payment rates, mitigation of new**

documentation burdens to justify the selected site of service, care quality, and beneficiary impact.

The ACC is not expert in the 266 musculoskeletal services proposed for initial migration, so cannot comment specifically on appropriateness of those APC assignments. However, no information was included in the rule to explain how APCs were selected. The ACC finds this concerning since cost reporting mechanisms and payment structures for IPPS and OPPS are entirely different. This is one aspect of the proposal that would benefit from greater transparency and a longer lead time and greater transparency.

Physicians already devote significant time and attention to selecting the appropriate site of service for procedures not on the IPO. These considerations include balancing patient input and preference with clinical factors and anticipated resource needs. Part of this process entails ensuring appropriate documentation and rationale is in place to validate the decision and protect against possible compliance or audit issues. A benefit of the IPO has been reduced administrative burdens for these compliance concerns because these were thought to be services that so obviously need the acuity of the inpatient setting that it would be unnecessarily risky to provide them in the outpatient setting. A fear of physicians is that this change will increase the burden and risk they and hospitals face to justify selecting a higher acuity setting. A related concern is that administrators or other payers may view the removal of the IPO as a requirement to provide services in the outpatient setting that would not otherwise be considered appropriate for that level of care. Specific proposals or guidance from the agency for navigating these aspects of site selection could make providers more comfortable with this change.

Little discussion was provided in the proposed rule regarding the impact on quality measurement programs already in place. For instance, acute myocardial infarction and heart failure mortality and readmission measures have been analyzed and publicly reported for inpatients for more than a decade. It is not clear that consideration was given to any methodological changes that may be warranted. The College recommends that CMS consider how to measure and maintain the quality and safety of services newly provided in the outpatient setting as procedures migrate. 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. Specific discussion and proposals regarding how the quality of care will be assured after potential movement to the outpatient setting would prepare providers for these changes.

Meaningful financial differences exist for patients when it comes to inpatient services. Medicare beneficiaries who are admitted as inpatients pay an inpatient hospital deductible—$1408 in 2020—for their share of costs during the first 60 days of a hospitalization. Any services that shift from inpatient Part A to outpatient Part B will require 20% copays for facility costs. The ACC did not see discussion of this change for beneficiaries in the economic impact analysis section and believes more attention should be devoted to this area of concern. While in most cases statute prevents the Part B copayment from exceeding the Part A hospital stay deductible for each service, there could still be out-of-pocket increases for beneficiaries if externalities mount pressure for services to be shifted to the outpatient setting.

Finally, CMS elsewhere in the proposed rule indicates a desire to push for site neutrality between hospital outpatient and ASC settings. The ACC sees the potential for parallel arguments to be made here when it comes to moving services from inpatient to outpatient settings. The ACC recognizes the opportunities to reduce costs through site-neutral payment policies but warns against rushing to the lowest possible payment. The same deference CMS proposes to give to beneficiaries' preferences and physicians' clinical knowledge and experience when it loosens policies that could shift services from the hospital inpatient setting to the hospital outpatient setting should also be given to patients physicians when they choose NOT to move to a lower acuity care setting.

Ambulatory Payment Classification (APC) Assignments

Cardiac Computed Tomography

The College remains concerned about payment stability for relatively low volume cardiac imaging services in the OPPS. Cardiac computed tomography (CT) (Code 75572-75574/APC 5571) has generally faced declining or unsteady payment levels in recent years. While the 2021 proposed rule maintains the same APC assignments for these services, payments are again slated to be reduced.

CPT Codes	CY 2021 Proposed	CY 2020	CY 2019	CY 2018	CY 2017
75572-75574	$181.41	$182.20	$201.74	$252.72	$264.90

The College recognizes that other factors such as hospital cost reporting contribute to inadequate payment amounts in the proposed rule calculations. Use of generic CT and MR cost center reporting systems will *chronically* underrepresent costs for these services because

they fail to account for enhanced clinical staff time and additional medicines used to perform the service. That means that meaningful cost data will never show a geometric mean cost high enough to support APC reassignment based on costs alone. Additionally, since these services have relatively small utilization in comparison to the rest of an assigned APC, they would not meaningfully impact payment rates within an APC even with a higher geometric mean cost. The trend noted above has created a sustainability spiral where payment reductions mean the services are provided at a greater loss every year.

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

A two-pronged approach could address this shortcoming in the immediate term and collect more accurate data for a durable solution. **First, the ACC urges CMS to place cardiac CT codes 75571 and 75572 with more resource intensive and clinically similar services in APC 5572, and 75574 in APC 5573 to stem facilities losses.** This request aligns with previous comments and information submitted by medical societies, including a survey of resource costs at institutions that was submitted to CMS earlier this year to bolster such a request and analysis commissioned by a data consultant. This payment is a more accurate estimation of the minimum cost of performing services. The alternative cost data was derived using a sample of centers with considerable systems and personnel expertise on the latest generation CT scanners. Thus, this data still underestimates mean procedural costs across the country. However, it better represents minimum costs than the cost data gathered under existing OPPS methodology. Cardiac CT has similar homogeneity with respect to resource utilization and cost as procedures grouped under APC 5572 to justify the recommended APC reassignment for the 2021 rulemaking period.

Second, CMS should implement changes that better capture the costs to provide cardiac CT. One approach would be to allow facilities to submit charges for cardiac CT using revenue codes that more accurately estimate costs. Current CMS regulation mandates that

cardiac CT be lumped into general diagnostic CT revenue codes. These revenue codes do not account for the specialized clinical staff, supplies, or capital equipment necessary to execute cardiac CT. The College believes that allowing cardiac CT services to be billed using cardiology or stress testing revenue codes will assign a more appropriate cost-to-charge ratio to current services and result in a cost estimation that more accurately reflects the true cost of cardiac CT. Alternatively, CMS could create line item HCPCS codes for supplies, cardiac technologist and cardiac nurse cost reporting to require facilities to make an entry for these resources. With those cost data available in two years, the Agency should then be able to reassess APC assignment based on collected cost data.

Cardiac Magnetic Resonance Imaging

As with cardiac CT, the College remains concerned about payment stability for cardiac magnetic resonance (MR) imaging (Code 75557/APC 5523, Code 75559/Code 5524, Code 75561/APC 5572, and Code 75563/APC 5573). CMS has generally faced declining or unsteady payment levels in recent years. While the 2021 proposed rule maintains the same APC assignments for these services, payments are again slated to be reduced.

CPT Code	CY 2021 Proposed	CY 2020	CY 2019	CY 2018	CY 2017	CY 2016	CY 2015
75557	$235.05	$233.01	$230.56	$245.22	$225.81	$273.54	$286.30
75559	$490.52	$481.53	$497.49	$245.22	$225.81	$441.36	$286.30
75561	$368.85	$381.81	$385.88	$456.34	$426.34	$454.32	$482.89
75563	$772.74	$680.74	$691.75	$681.83	$656.63	$1108.46	$1140.10

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

Before 2017, 75561 was placed in an APC with other MR imaging and angiography services with contrast that better aligned with clinical effort and costs. That APC was dismantled when a number of imaging APCs were restructured for 2017. Under the proposed APC structure for 2021, this code remains in APC 5572, grouped with services that are not clinically similar or similar in resource use. For example, CPT 75561 has little in common with CT of the abdomen or pelvis or MRI of the neck and spine. CPT 75561 is more comparable to services in APC 5573 (Level 3 Imaging with Contrast). **ACC recommends that CMS move CPT 75561 to APC 5573.**

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

Intravascular Lithotripsy (IVL) Procedures

Last summer, CMS issued new codes for IVL procedures performed in peripheral arteries in both the hospital outpatient and inpatient settings. At the time and under those new codes, Medicare payment rates for IVL procedures performed in the hospital outpatient and inpatient settings, respectively, were consistent with current payment levels for other similar peripheral artery interventional procedures.

Given the complexity of the lower revascularization procedures and due to the fact that the procedures can be performed alone or concomitantly, earlier this year CMS created four new C-codes for hospital outpatient billing. The codes in the following table account for the technology combinations but do not account for the vessel bed, as the description of the four codes includes “any vessel”:

HCPCS Code	Description
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed

Due to CMS assignment, is it possible for a hospital to be paid less for using IVL despite the IVL catheters being cost additive to the procedure. This payment disparity is especially evident in the tibial peroneal arteries as shown below:

CPT Code	Procedure	APC	CY 2021 Payment	HCPCS Code	Procedure	APC	CY 2021 Payment	Difference
37228	PTA	5193	$10,222	C9764	IVL + PTA	5192	$5,049	**($5,173)**
37230	PTA + Stent	5194	$16,348	C9765	IVL + PTA + Stent	5193	$10,222	**($6,126)**
37229	PTA + Atherectomy	5194	$16,348	C9766	IVL + PTA + Atherectomy	5193	$10,222	**($6,126)**
37231	PTA + Stent + Atherectomy	5194	$16,348	C9767	IVL + PTA + Stent + Atherectomy	5194	$16,348	$0

The ACC requests CMS increase the APC assignment levels by one for C9764, C9765, and C9766, which would then place the procedures in the table above at parity with how they are currently reimbursed without IVL. The ACC is concerned that hospitals will not only receive significantly less reimbursement if they use these codes, but also that they will have a disincentive to report, which eventually impact the Agency's data collection. Notably, the Advisory Panel on Hospital Outpatient Payment recently recommended the same reassignment, with the condition that the cost of IVL catheters is within 10% of other devices currently available.

CY 2021 New Technology APCs

Fractional Flow Reserve Computed Tomography (FFRCT)

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

CMS proposes to move code 0503T for FFRCT from New Technology APC 1511 for services with costs between $901 and $1,000 to New Technology APC 1510 for services with costs between $801 and $900 based on the latest cost data. The ACC appreciates the logic of CMS' proposal to set rates based on the collected cost data now that it has several hundred single frequency claims upon which to base APC assignment. However, this number continues to be below the $1,100 cost of the test based on invoices for the FFRCT service provided by members.

Similar to cardiac CT and cardiac MR, the ACC believes this discrepancy stems from flaws in the cost reporting methodology and payment calculation system in OPPS. In this instance, with only a few hundred claims, hospitals that have unintentionally underreported costs can easily bring down the geometric mean cost. Additionally, the formula for determining costs based on cost-to-charge ratios is likely to underrepresent costs, which is the reason a service known to have an invoice price of $1,100 can go through the system and come out with a geometric mean cost of $851. **The ACC recommends CMS not finalize this proposal, and instead assign 0503T to APC 1513 for services with costs between $1,101 and $1,200.**

Looking beyond 2021 rulemaking, the CMS and stakeholders will need to approach cost reporting and payment mechanisms for this service in innovative ways. FFRCT—and likely other services already in use or on the horizon—does not fit well into the cost reporting and payment structures of the OPPS. FFRCT requires a modest use of facility clinical staff. Additional images are not obtained. Supplies are not consumed. Equipment is not further utilized. Instead, complex computer analysis examines already obtained images to derive a new diagnostic report with important clinical insights that clinicians utilize to better guide care for select patients. The cost of the service to the facility is the price they pay to the vendor. It

may be acceptable to leave services like this assigned to new technology APCs that approximate the costs of the service price indefinitely. It may be acceptable to create individual APCs for each technology based on demonstrated costs. It may be possible to group similar services that execute additional processing together. Whichever solution is deployed, it should not be the case that facilities lose money each time they provide high quality care. The ACC looks forward to continuing to engage in finding meaningful solutions that can ensure facilities can provide high quality care with innovative technology.

Interatrial Shunt Procedures

To compensate for care during randomized clinical trial of interatrial shunt devices, CMS established new technology HCPCS codes (C9760 and C9758) to report a novel chronic heart failure treatment using interatrial shunt technologies in two trials of different design. Both IDE devices have received FDA Breakthrough Device Designation. ACC urges CMS to ensure these interatrial shunt procedures are assigned to New Technology APCs that appropriately reflect the costs related to these procedures. CMS could rely on manufacturers' cost data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for these procedures. Optimizing the rate setting will enable the IDE studies to enroll and treat patients while generating real-world claims data. Resolution of any shortcomings will enhance care for appropriate patients with chronic heart failure in trials while protecting the Medicare program.

Level of Supervision of Pulmonary, Cardiac, and Intensive Cardiac Rehabilitation Services

In CY 2020 rulemaking, CMS implemented a policy to change the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and critical access hospitals. However, some groups of services were not subject to the change in the required supervision level and those services continue to have a minimum default level of supervision that is higher than general supervision.

Responding to the COVID-19 PHE, CMS specified in March that the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. This policy was adopted on an interim final basis for the duration of the PHE. Reflecting on the value of this change, CMS now proposes that these policies are appropriate outside of the PHE and should apply permanently.

This change would permanently allow direct supervision provided by the virtual presence of the physician. **The ACC supports this change which will continue to improve access for patients and reduce burden for providers after the end of the PHE.** Telecommunications technology can be used in a manner that will facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished.

CMS further clarifies that virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. **The ACC urges CMS to reconsider this proposal and align standards for virtual direct supervision of these rehabilitation services with its proposal in the physician fee schedule** that the direct supervision requirement can be met "by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure." Many of the same arguments that have been made seeking general supervision of these services in the past would still apply to the solution virtual direct supervision solution CMS proposes. This modification will allow meaningful flexibility that enhances the care of patients completing these rehabilitation services.

Prior Authorization

In last year's rulemaking, CMS established a prior authorization process for certain hospital outpatient department (OPD) services. This year, CMS proposes the addition of the following two categories of services to the prior authorization process beginning for dates of service on or after July 1, 2021: (1) cervical fusion with disc removal and (2) implanted spinal neurostimulators, as seen in the table below.

CPT Code	Description	Category
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial	Cervical Fusion with Disc Removal
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck, anterior approach, each additional interspace	Cervical Fusion with Disc Removal
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin	Implanted Spinal Neurostimulators
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver	Implanted Spinal Neurostimulators
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver	Implanted Spinal Neurostimulators

CMS justifies adding these services to the prior authorization process based upon their determination that there has been an unnecessary increase in the volume of these services.

In last year's rulemaking, CMS recognized the need to establish baseline measures for comparison purposes, including, but not limited to, the yearly rate-of-increase in the number of OPD claims submitted and the average annual rate-of-increase in the Medicare allowed amounts. This year, CMS is acting on these regulations and reviewed over 1.2 billion claims related to OPD services during the 12-year period from 2007 through 2018 in order to obtain the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 2.8 percent.

In the past, ACC has recommended that CMS should not consider blanket prior authorization as a method for controlling overutilization of services under the OPPS. **The ACC still takes this position and 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.**

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.

Prior authorization should only be used if CMS can guarantee that it will not create additional burden for clinicians and patients. 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.[6] 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. The Agency should consider numerous issues with prior authorization that are currently experienced through Medicare Advantage (MA) and other health plans. Doctor visits are commonly delayed and/or extended while waiting for authorization decisions leading to multiple hour visits and rescheduled care. 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. These challenges are all present under normal circumstances.

[6] https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf

While the proposed changes are not subject to implementation until later in 2021, the ACC believes there is much uncertainty as to how long the PHE will last, and is concerned that these regulations will make an already challenging climate even more difficult, as its planned implementation is expected around the time many hope to be 'returning to normalcy' but will still be experiencing financial struggles from the current pandemic. In light of the COVID-19 public health emergency (PHE), the ACC urges CMS to reconsider this proposal and provide prior authorization flexibilities, which many other insurers have implemented during the PHE. While the ACC greatly hopes that the country does not experience a resurgence in COVID-19 cases later this year, the ACC cannot guarantee this does not happen, nor that another national emergency declaration or further state-level safeguards be issued.

Currently, the PHE has forced the temporary suspension of elective procedures and decrease in non-time-sensitive services, which has resulted in many care settings reducing the amount of administrative positions in hospitals. Accordingly, the reduction in administrative resources and the high demand in hospital for PHE-related care has made it quite burdensome to process the required paperwork for prior authorization processes to occur. Understandably, many insurers are waiving prior authorizations for diagnostic tests and services. The College believes this flexibility allows financial concerns to ease, as well as reduces administrative relief by reducing delays in providing patients with the appropriate care. The entire medical community is in need of additional support and time in adjusting the demands the PHE brings and the aftermath once the PHE is over. **The College asks CMS to consider the short- and long-term affects of COVID-19 on patients, physicians, and the medical community as a whole, and asks the CMS to minimize and delay prior authorization requirements.**

Separate Payment Following the End of the Pass-Through Period

In this proposal, CMS solicits comments on providing separate payment following the end of the pass-through period for medical devices with reduced utilization during the PHE. Currently, medical devices are only eligible for transitional passthrough payments for a maximum of three years. Currently, seven device categories are eligible for transitional pass-through payment. In response to concerns expressed by stakeholders, CMS requests comments on using its authority to provide separate payment for an undefined period of time after passthrough status ends for these device categories to account for the period of time that device utilization was reduced.

The ACC is concerned that devices on pass-through status are frequently used during elective procedures. Unfortunately, device payment is calculated based on usage and the reduced volume would negatively impact the expected payment down the line, as elective procedures have been reduced, if not eliminated in some regions, due to the PHE. **The College recommends CMS provide separate payment following the end of the pass-through period for at least 12 months following the end of the PHE, adding additional time for each month the PHE endures longer than 12 months. This timeframe would help account reduced utilization during the PHE.**

Physician-Owned Hospital Expansion at High Medicaid Facilities

Continuing to seek ways to reduce administrative burden under the Patients Over Paperwork Initiative, CMS has identified that certain statutory provisions regarding restrictions to facility capacity expansion were applied to "high Medicaid facilities" are not explicitly required under current law. Rather, they were applied using the Secretary's authority to create consistency with Congress' intent to prohibit expansion of physician-owned hospitals generally.

Since Congress did not mandate that high Medicaid facilities require the same treatment, CMS would alter regulations it believes create unnecessary burden on high Medicaid facilities. Specifically, CMS proposes (1) to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every two years, (2) to remove from high Medicaid facilities the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds, and (3) the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus.

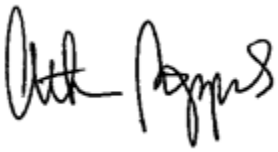
The ACC has generally supported legislative and regulatory changes that allow physicians to more options to care for patients in various and appropriate sites of service, and specifically supported changes that would allow expansion of physician-owned hospital capacity. The ACC appreciates this proposed burden reduction effort.

Conclusion

CMS consideration of the comments in this letter is appreciated. The ACC looks forward to ongoing engagement with CMS to develop policies that support clinicians' ability to focus on delivering high quality care to patients. The ACC acknowledges the tremendous thought and

planning CMS is undertaking to improve the healthcare system. Should you or staff need additional information or have clarifying questions, please contact Claudia Vasquez, Associate Director of Medicare Payment & Quality Policy, at cvasquez@acc.org.

Sincerely,



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