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Heart House
2400 N Street, NW Washington, DC 20037-1153 | USA
202-375-6000 | 800-253-4636 | Fax: 202-375-7000
www.ACC.org

September 13, 2022

The Honorable Chiquita Brooks-LaSure
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; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Submitted via www.regulations.gov

Dear Administrator Brooks-LaSure:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the CY2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule. The College's comments focus on APC assignments and policies, telemedicine, the software as a service RFI, the new Rural Emergency Hospital Quality Reporting program, and the ASC payment system.

The ACC is the professional home for the entire cardiovascular care team. The mission of the College and its more than 56,000 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.

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Proposed New Technology APCs

Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

CPT codes 78431, 78432, and 78433 that describe cardiac PET/CT studies have been assigned to New Technology APCs since their implementation in 2020. 78431 has been assigned to APC 1522 for services with costs between $2001-$2500 with a payment rate of $2,2540.50. 78432 and 78433 have been assigned to APC 1523 with a payment rate of $2,750.50 for services with costs between $2501-$3000. No claims data were available for these services during CY 2021 or CY 2022 rulemaking. For CY 2023 rulemaking, CMS proposes to use CY 2021 claims data to set payment rates for these three codes. **The ACC supports the proposed APC assignment for 78431 but urges CMS to delay changes to APC assignment for 78432 and 78433.**

CPT code 78431 had over 18,000 single frequency claims in CY 2021. The geometric mean for these claims was approximately $2,509, above the cost band for APC 1522. CMS proposes to reassign 78431 to APC 1523 with a payment rate of $2,750.50, recognizing the costs exceed those meant for the cost band in APC 1522. **The ACC supports this change for CY 2023; with over 18,000 claims, it appears based on a solid footing.**

In contrast, CPT code 78432 had only five single frequency claims in CY 2021. CMS proposes to apply its universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to four years of claims data. Through that analysis, CMS found an arithmetic mean cost of $1,899 and proposes to reassign 78432 to APC 1520 for services with a cost between $1801-$1900 with a payment rate of $1,850.50.

Similarly, CPT code 78433 had 954 single frequency claims in CY 2021. CMS proposes to use the geometric mean cost of $1,999 to reassign 78433 to APC 1521 for services with a cost between $1901-$2000 with a payment rate of $1,950.50.

The ACC urges CMS not to implement these two proposed APC reassignments, and instead leave both 78432 and 78433 assigned to APC 1523 in CY 2023. The ACC does not believe adequate claims data—five and 954 single frequency claims—is adequate to set rates in this instance. Something is lacking in the available cost data. From a clinical workflow perspective, 78432 and 78433 consume more resources than 78431. 78431 requires two separate full procedures and using two separate injections of a radiotracer for perfusion studies. 78432 and 78433 require those same steps, however, instead of two injections using the same perfusion radiotracer, two different tracers are injected for the image acquisition, one for perfusion and one for metabolic study. The second tracer used for metabolic studies—fluorodeoxyglucose (FDG)—requires more prep time than those used for perfusion studies. With a similar, but enhanced, clinical staff and radiotracer workflows to 78431, it is not appropriate for 78432 and 78433 to be assigned to APCs with payments lower than 78431. Part of that problem here could be the dramatically lower volumes of 78432 and 78433 in comparison to 78431. With CY 2021 being the first year on which CMS had data available for these

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services, it would be reasonable to not make these disruptive changes at this time, instead collecting another year of cost data.

APC-Specific Policies

Fractional Flow Reserve Derived from Computed Tomography (FFRCT)

CMS proposes to assign FFRCT (CPT Code 0503T) to clinical APC 5724 (Level 4 Diagnostic Tests and Related Services) with a payment rate of roughly $961. Although CMS claims to "have sufficient single frequency claims from these three years to have a reliable estimate of the cost of the service," the ACC continues be concerned that the calculated cost of the service continues to be below the $1,100 cost of the test based on invoices for the FFRCT service provided by members.

Similar to other imaging services upon which the ACC has commented in recent years, the ACC believes this discrepancy stems from flaws in the cost reporting methodology and payment calculation system in OPPS. In this instance, with 1,682 single frequency claims, facilities that have unintentionally underreported costs reduce the geometric mean cost. Additionally, the formula for determining costs based on cost-to-charge ratios could underrepresent costs, which is the reason a service known to have an invoice price of $1,100 can demonstrate a geometric mean cost of $768 in CY 2018, $808 in CY 2019, and $827 in CY 2021.

Despite this discrepancy, **the ACC cautiously supports CMS's proposal to assign FFRCT to APC 5724.** FFRCT is a diagnostic service that produces data on the effect of coronary artery disease on blood flow, which helps physicians determine the most appropriate treatment for their patient. From a clinical perspective, this APC family seems to be an appropriate fit.

While the proposed payment rate of $961 does not cover the $1,100 cost of the service, assignment to a clinical APC should bring a degree of payment stability. Facilities and physicians will be more likely to utilize FFRCT with assignment to APC 5724 and the added certainty the payment rate provides.

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 2023 proposed rule maintains the same APC assignments for these services, payments are again slated to be stagnant and reduced in comparison to just a few years ago, when payment in APC 5571 was 44% higher, about $265 in 2017.

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

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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 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 75572, 75573, and 75574 with more resource intensive and clinically similar services in APC 5572 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 2022 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

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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 (MRI)

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). Cardiac MRI has generally faced declining or unsteady payment levels in recent years. While the 2023 proposed rule maintains the same APC assignments for these services, payments are slated to be essentially flat for 75561 for and increased slightly 75563. Neither payment approaches either the median or geometric mean costs for these services.

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 2022, 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 like 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.

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Percutaneous Venous Mechanical Thrombectomy Complexity Adjustment

Criteria for complexity adjustment from an originating Comprehensive APC (C-APC) to the next higher paying C-APC in the same clinical family allow for services reported together more than 25 times that violate the 2 times rule to be paid a higher, more appropriate rate. Addendum J presents the calculations for these combinations. The ACC identified the combination of percutaneous venous mechanical thrombectomy (37187) and venous transluminal balloon angioplasty (37248) as two important services that meet the frequency threshold and are very close to meeting the specified cost threshold. The subset service combination frequency is 224 and the subset combination geometric mean cost is $15,197.11. The cost threshold to trigger complexity adjustment is $15,962.16.

Since 2019, CPT code 37238 (venous stent) and 37187 (venous thrombectomy) have led to a complexity adjustment based on both frequency and cost thresholds. These services are similar to the combination of 37187 and 37248 mentioned above. 37187 with 37248 treat similar patients and consume similar resources, but without the placement of a stent. In 2021, venous balloon angioplasty (37248) and venous thrombectomy (37187) were performed together in 33% of the claim subsets. Clinical coherence is critical when evaluating these codes. The clinical presentation of patients, the procedure preparation, time, skill, and intensity are similar whether performing a venous thrombectomy, venous balloon angioplasty, or placing a venous stent alone or in combination together, and therefore should have the same complexity adjustments applied. Based on the clinical coherence of these similar procedures and resource utilization, **the ACC requests that CMS apply the complexity adjustment when 37187 and 37248 are reported together, moving these procedures from APC 5193 to APC 5194**.

Nonrecurring Policy Changes

Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

Cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) programs are an important part of recovery for those with chronic heart and lung disease and who deal with acute events and exacerbations of their conditions. After hospitalization, it is the standard of care to provide outpatient cardiac or pulmonary rehabilitation services, consisting of exercise and education. These vital programs have been shown to reduce rehospitalization and all-cause mortality, as well as improve physical function, quality of life and lifestyle choices so patients may better self-manage these chronic conditions.

We appreciate the changes that CMS made to 42 CFR 410.2(a)(1)(iv)(D) in previous rulemaking to provide the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation (PR), cardiac rehabilitation (CR), and intensive cardiac rehabilitation (ICR) services to be met through virtual presence via 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 has enhanced access to care by keeping Medicare beneficiaries safe during the worst part of the pandemic and enabling them to receive CR and PR services in the home setting

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under the Hospital Without Walls waivers. Beneficiaries living in rural and underserved areas have particularly benefited from the wavier policy by eliminating the need to travel hundreds of miles in some cases to receive care, resulting in improved adherence to the protocols.

Although CMS confirms in the proposed rule that an individual's home will no longer be a telehealth site when the PHE ends, Medicare beneficiaries can continue to receive services in the hospital outpatient setting as well as other settings deemed "originating sites" in the statute. For that reason, CMS is looking to effectuate a similar policy for hospital outpatient services around direct supervision through virtual presence like the policies in the PFS CY 2023 proposed rule. CMS seeks comment on whether to continue direct supervision through virtual presence through the end of CY 2023. CMS also seeks feedback regarding safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

The ACC supports continuing direct supervision through virtual presence for PR, CR and ICR programs through the end of CY 2023 at a minimum but has serious concerns about beneficiary access and adherence to these valuable programs if CMS chooses not to extend the policy or make permanent direct supervision through virtual presence via real-time, audio/visual telecommunications technology after the PHE ends. **The ACC recommends CMS make permanent direct supervision through virtual presence via real-time, audio-visual telecommunications technology in the hospital outpatient setting so Medicare beneficiaries can continue to receive cardiac and pulmonary rehabilitation services that improve their lives.**

Coding and Payment for Category B Investigational Device Exemption (IDE) Clinical Studies and Devices

Medicare may pay for routine care items and services furnished in an FDA-approved Category A (Experimental) study if CMS determines that Medicare IDE study criteria are met. However, Medicare does not make payment for the Category A device itself, which his excluded from coverage by statute. Further, Medicare may pay for both the device and routine care items/services of a Category B (Nonexperimental/investigational) study that meets Medicare IDE study criteria. CMS describes recent efforts to create codes that include both the intervention and control arms for double-blinded Category B IDE studies in a manner that prevents unblinding for study participants through claims data.

For CY 2023, CMS proposes to make a single, blended payment for both the intervention and control groups of qualifying Category B IDE studies to preserve the scientific validity of such studies. This blended rate would apply to the combined intervention/control code. This would prevent the possibility of unblinding should those study participants receiving a placebo/sham have a lesser Medicare payment due to the absence of the Category B device.

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The ACC supports CMS's proposal for the coding and payment for Category B IDE studies. The maintenance of the blind in randomized clinical trials is crucial to the validity of the study. The differential reimbursement is a potential source of breaking the blind, and the foresight by CMS to adjust coding and payment to maintain blind is admirable. The attention to scientific validity outweighs the small chance for differential reimbursement based on randomization, should a research site happen to perform more placebo/sham services than intervention services.

Payment for Software as a Service (SaaS)

CMS describes the advance and increasing use of SaaS algorithm-driven services that assist clinicians in making clinical assessments. Providers pay for SaaS on a per-use or subscription basis. This is in contrast to other software which has traditionally been purchased with hardware acquisitions or as add-ons to enhance features/services. New CPT codes have been developed for a variety of SaaS procedures. In many instances, the costs associated with the SaaS procedures exceed the costs of the imaging service with which they would be billed, prompting CMS to create C codes to describe SaaS procedures as standalone services in instances when CPT has created add-on codes to describe SaaS procedures.

Citing the heterogenous, novel, and evolving nature of SaaS technologies, CMS states it is challenging to compare SaaS procedures to existing medical services for the purposes of determining clinical and resource similarity. Therefore, the Agency seeks public comment on several aspects of payment policy that would broadly apply to SaaS procedures. The ACC appreciates the Agency's efforts to devise a cogent strategy in this space and offers preliminary thoughts on the questions posed in the rule. However, more work and policy need to be done in this space, and the ACC looks forward to additional engagement on this topic.

How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the physician fee schedule?

The CPT Editorial Panel process could generally be relied upon to identify services which are distinct from the underlying, base test or professional service fee or needing physician judgment and quality oversight for clinical adjudication. In instances where CPT is not utilized for some reason, it seems likely that stakeholders have every incentive to be in contact with CMS to identify appropriate coding solutions to recognize which analyses are distinct.

More broadly, the ACC is concerned that many new SaaS technologies could quickly be seeking distinct coding options for services that fit the criteria to be a distinct service but may also have similarities to software that is purchased by an imaging lab or already included in equipment and subscriptions used to make similar assessments.

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How to identify costs associated with SaaS?

While even in this rule the ACC has noted that there are apparent instances of cost underreporting, it seems the existing infrastructure for facilities to report costs to CMS could be utilized to continue to do this for SaaS. Modifications may be needed to incorporate novel elements.

At a different level, the ACC remains uncertain what constitutes an appropriate mechanism to set pricing for these services. Is it the cost to research, develop, and implement a machine-learning algorithm amortized across some number of expected units of service to derive a return of some percentage on the required investment? If SaaS can avoid downstream costs, would the rate be the downstream costs saved? If so, how would downstream cost savings be assessed, as services are usually assessed by costs to deliver? Perhaps the price is simply whatever the market will bear? In every instance with which ACC is familiar, it is unknown what determines the price a facility or practice is billed for an individual SaaS. In addition to the traditional components of supplies, equipment, and labor, the price of a unit of SaaS analysis appears to be a black box for which derivation of the invoiced price is unknown.

Decisions will have to be made about whether the "costs" are represented by a subscription or per-click fee as opposed to inherent in purchased software or equipment. If a result obtained through SaaS can also be obtained through other manipulation of already-owned software tools, are the additional costs of that effort added to the traditional version of the service, or are they considered in the same pool as the SaaS? Depending on the rate charged for SaaS, the other-derived versions may be much more affordable and there would be reasons and incentives to want to identify low-cost options.

How might these services be available and paid in other settings?

In the physician fee schedule and physician office setting, cardiology has seen these services be more or less available depending on whether the payment rate covers the cost of the services. In the most cited example, the fee for a scanning analysis of existing CT data used to derive a computed FFRCT is $1,100 as shown on many invoices. Currently, these services are paid as Category III CPT codes using a crosswalk-derived rate of about $958, which still does not cover the cost a practice incurs. However, when these services are promoted to Category I CPT codes, CMS will consider recommended supply and equipment costs for the service and process them through the practice expense formula. Because of the practice expense scaling factor, even assuming the $1,100 invoice is accepted, the payment rate will be far lower than the cost a practice incurs for obtaining this computer analysis.

How should payment strategies for SaaS align across settings of care?

As expressed in comments on the physician fee schedule regarding Medicare Economic Index revisions, the ACC is concerned about the potential shift of resources from the work of patient care provided by clinicians to overhead and practice expense costs. Payment strategies should align

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across settings to ensure resources for technology do not cannibalize resources for human clinicians and caregivers.

What payment approach(es) could be scaled as SaaS grows and expands beyond imaging services?

CMS posits payment could be packaged into new HCPCS codes that broadly describe the diagnostic imaging service and any SaaS procedure performed. Alternatively, composite APCs could provide a single payment for groups of services performed together during a single encounter. Or, HCPCS codes that describe imaging and SaaS combinations could be assigned to New Technology APCs that would pay for both services. The ACC believes any of these approaches could be scaled, but each is technically complex and the final decision will reflect the intent of the implementation. Perhaps CMS could give schematic examples of how it believes each of these options would be implemented and standardized across categories of SaaS and how it believes such options would be reevaluated as each specific software rapidly evolves over short periods of time for stakeholders to react to in future rulemaking or RFIs on the topic.

Rural Emergency Hospital Quality Reporting (REHQR) Program Measures

As CMS is proposing to create a new REHQR Program, several new measures are under consideration for use in the program. Three of these measures have been in use in the Hospital Outpatient Quality Reporting (OQR) Program.

OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.

This chart-abstracted process measure calculates the percentage of ED acute myocardial AMI patients with ST-segment elevation on the electrocardiogram (ECG) closest to arrival time receiving fibrinolytic therapy during the ED stay and having a time from ED arrival to fibrinolysis of 30 minutes or less. We have concerns about this measure due to low reporting rates. STEMI care should be oriented toward rapid access to primary PCI. Sometimes it takes more than thirty minutes to determine if primary PCI access will be possible (e.g., determining weather delays for transport, etc). A better metric would be attestation of an emergency department MI protocol that details the site-specific primary PCI pathway and the back-up fibrinolytic therapy pathway.

OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.

We are concerned that this measure also has relatively low reporting rates. Door-in/Door-out (DIDO) time should be less than 30 minutes, with time from initial presentation to PCI less than 120 minutes. For rural hospitals, meeting both OP-2 & OP-3 is much more of a challenge, and there will be more variability based on specific geographic location of the rural facility. For example, it is easy to imagine a rural hospital that routinely can revascularize its STEMI patients within 120 minutes by transferring to another PCI site, but that rural facility's DIDO is always greater than 30 minutes because of the inherent wait for arrival of helicopter transport. We certainly would not want

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those patients getting fibrinolytic therapy to "win" on a STEMI quality metric when the real objective (PCI within 120 minutes) is attainable.

OP-2 & OP-3 were removed from the hospital OQR Program. CMS has replaced these measures with a new cCQM (OP-40) that combines the two into a measure of timeliness and appropriateness of STEMI care. We believe this seems like a reasonable replacement, but it remains unclear why CMS is soliciting feedback on these three measures if the STEMI eCQM (OP-40) is designed to replace OP-2 and OP-3. CMS should clarify that if a rural hospital that does not do PCI, are OP-2 and OP-3 remaining, or being combined? If they are being combined, the combination of <30 (lytic) or <45 (transport) is reasonable.

ASCQR Program Request for Comment on Measure Sets

CMS is considering a potential future specialty centered approach for the ASCQR Program, which would allow quality-related data for ASCs to be reported on a customizable measure set that more accurately reflects the care delivered in this setting and accounts for the services provided by individual facilities. It would also allow for the creation of a specialty-specific set of measures, or specialized tracks of measures for facilities to choose from. Given the ambulatory nature of the kind of procedural care that occurs in ASCs, there needs to be specific measures created based on the work performed. (There could be some general measures, like Emergency Room utilization within 24 hours of ASC-care.) But the ASC that is doing single level spine surgery will be very different than the ASC one day doing PCIs. We believe the best course of action in developing or selecting metrics would rely on the input and expertise of relevant professional societies. Current measures available such as in MIPS may not capture the specific concerns for ensuring quality in an ASC-setting.

Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

In response to stakeholder comments, including the ACC, CMS proposes new policy to address the payment differential that exists between comprehensive-APC-assigned code combinations eligible for complexity adjustments under the OPPS and the same code combinations that are not eligible for complexity adjustment under the ASC payment system. Currently payment for add-on procedures performed in the ASC setting are packaged with payment for the primary procedure. Such a differential could potentially create financial disincentives for providers to offer these services in the ASC setting, limiting beneficiary access to these service in ASC settings.

To address this payment differential and enhance access to care, CMS proposes that combinations of a primary procedure code and add-on codes that are eligible for complexity adjustment under the OPPS would also be eligible for complexity adjustment in the ASC setting. CMS would create a new

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Joseph Edward Marine, MD, MBA, FACC

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C code for each eligible code combination that describes the primary and the add-on procedure(s) performed. These C codes would receive a higher OPPS complexity-adjusted C-APC payment rate that reflects that the code combination is a more complex and costlier version of the performed procedure. These codes would be updated each year as needed. C codes would be subject to all ASC payment policies.

The ACC supports this proposal to create a complexity adjustment payment solution in the ASC setting that appears to parallel that of the OPPS. A number of important cardiovascular services and related add-on procedures performed in the ASC setting fit the qualifying criteria for complexity adjusted payment and would be included for 2023. The ACC has previously expressed concern that packaging and a lack of complexity adjustment in the ASC setting would limit access to ancillary fractional flow reserve (FFR) and intravascular (IVUS) imaging performed with diagnostic cardiac catheterization and percutaneous coronary intervention (PCI) services. The new complexity adjustments would address payment shortcomings when these ancillary procedures are performed with diagnostic cardiac catheterization.

Unfortunately, the way the complexity adjustment standards are set, PCI performed with ancillary services will continue to fail to qualify for complexity adjustment in both the OPPS and the ASC setting. Either the construct of the comprehensive APCs, or the cost reporting that informs them, or both, may be preventing appropriate facility payment for these adjuncts when performed in support of PCI. One aspect of the tables in Appendix J is the low volume of combination frequency on which payment policy decisions are made for some services. In some instances combinations occurred in the single digits. However, interventional cardiologists performed over 40,000 fractional flow reserve measurements (93571) in the OPPS setting. We would expect a significant portion of those to be performed with the largest diagnostic catheterization service (93458) that was performed over 200,000 times in the OPPS setting. However, the complexity analysis in Table J shows the combination to have only occurred 6,646 times when a significantly higher portion of diagnostic catheterizations would be expected to be performed with fractional flow reserve. It appears to ACC that some data reporting shortcoming could be preventing accurate assessment of facility costs for these combinations of services.

One mechanism by which this might occur is that when hospitals are billing for add-on codes like FFR or IVUS, they are also billing the diagnostic catheterization codes (J1 primary service) as well as the PCI code (J1 primary service) on the same claim. Because of the hierarchy for how multiple J1 primary services on a claim under the C-APC system are paid, the PCI code is "higher" than the diagnostic catheterization code. The PCI code is deemed the primary J1 service and the diagnostic catheterization code as the secondary J1 service. Evaluation of complexity adjustment is based on those two code combinations, not FFR or IVUS. Much of the volume for the purpose of complexity adjustment evaluation expected from a code combination of FFR or IVUS is shifted to the code combination of PCI and diagnostic catheterization code. The ACC believes this obstacle to thorough data collection and analysis warrants a solution to further enhance the complexity adjustment process.

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Another element the ACC believes warrants further consideration is whether the cost threshold may not be appropriate, perhaps warranting exceptions in some instances. The current requirement for *a modeled geometric mean cost that is a factor of 2 or greater than the comprehensive geometric mean cost of the lowest significant HCPCS in the primary procedure's APC when modeled without the application of complexity adjustments* may simply be too high a bar. The ACC does not have a specific recommendation for what might be more equitable but suggests further consideration of that threshold would be appropriate.

Conclusion

Thank you for your time and consideration of these comments, and the work by CMS staff who administer the program. Please contact Matthew Minnella, Associate Director for Medicare Payment Policy, at mminnella@acc.org if you need any additional information.

Sincerely,

Edward Fry, MD, FACC
President

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Edward T. A. Fry, MD, FACC

Vice President
B. Hadley Wilson, MD, FACC

Immediate Past President
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