



September 6, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

Dear Administrator Brooks-LaSure:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the CY 2024 Medicare Hospital Outpatient Prospective Payment System (OPPS) for hospital outpatient and ambulatory surgical center payment policy, and other policies addressed in this proposed rule. The College's comments focus on Ambulatory Payment Classifications (APCs), Hospital Outpatient Quality Reporting (OQR) Program Quality Measures and enforcement of hospital transparency requirements.

The ACC is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source of professional medical education for the entire cardiovascular care team since 1949, and now with more than 56,000 members from over 140 countries, the ACC credentials cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards, and guidelines.

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 had been assigned to New Technology APCs since their implementation in 2020 before CMS made adjustments to these based on cost data for CY 2023 rulemaking. Starting in 2020, 78431 was assigned to APC 1522 for services with costs between \$2001-\$2500 with a payment rate of \$2,250.50. 78432 and 78433 were 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 moved 78431 to APC 1523 for services with costs between \$2501-\$3000,

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78432 to APC 1520 for services with a cost between \$1801-\$1900, and 78433 to APC 1521 for services with a cost between \$1901-\$2000. Each of these changes were finalized, despite concerns from ACC in comments that the latter two changes to 78432 and 78433 were premature based on the small amount of data and the clinical and cost similarities among all three procedures.

In the CY 2024 proposed rule, CMS again proposes adjustments to these services' new technology APC assignments. For CY 2024 rulemaking, CMS moved 78431 to APC 1522 for services with costs between \$2001-\$2500 and 78432 to APC 1518 for services with a cost between \$1601-\$1700. 78433 would remain in APC 1521 for services with a cost between \$1901-\$2000.

CPT code 78431 had over 22,000 single frequency claims in CY 2022. The geometric mean for these claims was approximately \$2,300, below the cost band for APC 1523. CMS proposes to reassign 78431 to APC 1522 with a payment rate of \$2,250.50, recognizing costs below those meant for the cost band in APC 1522. With over 22,000 claims, this proposal appears based on a large volume of information and appears to be reliable. **Nonetheless, the ACC opposes this proposed change. Increasing payment for a service \$500 one year and then reducing it \$500 the next creates significant disruptions for service lines. The ACC urges the agency to consider an intermediate solution that allows greater stability and predictability.** One option could be to utilize several years of cost data—not unlike the low volume APC policy—to smooth the potential for large fluctuations.

A second could be to utilize new technology APCs with narrower bands. New technology APCs 1503-1521 proceed in \$100 increments, while those from 1522-1537 proceed in \$500 increments. It is not obvious that increments should grow to \$500 starting at a \$2001 threshold. Dropping payment from \$2750.50 to \$2250.50 is a more than an 18% payment reduction. In other areas, CMS has seen value in providing stability and avoiding large payment swings. Starting in the CY 2023 inpatient prospective payment system rule, CMS began a policy to provide stability by limiting weight reductions to no more than 10% in a given year. A similar policy—that could be achieved with narrower increments or a transition policy limiting reductions to 10%—in the OPPS setting would minimize disruption here.

CPT code 78432 had only six single frequency claims in CY 2022. 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 \$1,658 and proposes to reassign 78432 to APC 1518 for services with a cost between \$1601-\$1700 with a payment rate of \$1,650.50.

CPT code 78433 had over 1200 single frequency claims in CY 2022. CMS proposes to use the geometric mean cost of \$1,960 to maintain assignment of 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 this APC reassignment of 78432, and instead leave 78432 assigned to APC 1520 in CY 2024. The ACC does not believe the available claims data—six single frequency claims—is adequate to set rates in this instance. Something is lacking in the

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available cost data. From a clinical workflow perspective, 78432 consumes more resources than 78431. 78431 requires two separate full procedures and uses two separate injections of a radiotracer for perfusion studies. 78432 requires 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 similar, but enhanced, clinical staff and radiotracer workflows to 78431, it is not appropriate for 78432 to be assigned to an APC with payments lower than 78431. Part of the problem here could be the dramatically lower volumes of 78432 in comparison to 78431. With CY 2022 being only the second year on which CMS had data available for these services, it would be reasonable to not make disruptive changes at this time, instead collecting another year of cost data.

Cardiac Computed Tomography

The College remains concerned about payment stability for relatively low volume cardiac imaging services in the OPPS. Cardiac computed tomography (CT) (Codes 75572-75574/APC 5571) has generally faced declining or unsteady payment levels in recent years. While the 2024 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 50% 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 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.

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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 2024 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 (MRI)

As with cardiac CT, the College remains concerned about payment stability for cardiac magnetic resonance (MR) imaging (Code 75557/APC 5523, Code 75559/APC 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 2024 proposed rule maintains the same APC assignments for these services, payments are slated to be essentially flat for 75561 for and decreased 5% for 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

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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 2024, 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.

Fractional Flow Reserve Derived from Computed Tomography (FFRCT)

CMS proposes to assign FFRCT (CPT Code 7X005) to clinical APC 5724 (Level 4 Diagnostic Tests and Related Services) with a payment rate of roughly \$1,009. The new Category I CPT code for this service (7X005) goes into effect January 1, 2024, and replaces the Category III Code (0503T) used previously to bill for FFRCT. Insofar as assignment to APC 5724 is the same APC to which the Category III Code was assigned in CY 2023, the ACC agrees with the proposal. 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.

The proposed payment rate of \$1,009 still does not cover the cost of the service, despite submitted hospital cost data. Providers pay \$1,100 for the software scanning analysis in addition to enhanced facility costs for clinical staff, supplies, and equipment. Assignment to a clinical APC will offer payment stability, but the ACC remains concerned that OPPS payment limitations could limit access if the service must be offered at a loss. A different outcome could be that facilities negotiate lower prices that reflect the OPPS payment amount, but that would also reduce the cost data collected by CMS in future years that drives even lower payment, producing a declining cost/payment spiral. The ACC urges careful monitoring of the impact of this APC assignment on access to care.

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Comprehensive APC (C-APC) Complexity Adjustment Policy

A number of important cardiovascular services and related add-on procedures performed in the OPPI and ASC settings fit the qualifying criteria for complexity adjusted payment and would be included for 2024. The ACC remains concerned that packaging and a lack of complexity adjustment will limit access to ancillary fractional flow reserve (FFR) and intravascular (IVUS) imaging performed with percutaneous coronary intervention (PCI) services.

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 OPPI 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 45,000 fractional flow reserve measurements (93571) in the OPPI setting in 2021. We would expect a significant portion of those to be performed with the largest diagnostic catheterization service (93458) that was performed nearly 230,000 times in the OPPI setting. However, the complexity analysis in Table J shows the combination to have only occurred 5,934 times when a significantly higher portion of diagnostic catheterizations would be expected to be performed with fractional flow reserve.

Similarly, the combination of 93571 with stent PCI (C9600) occurred only 218 times when clinical practice and the experience of cardiologists dictates that alignment should occur much more often. 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.**

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, firm recommendation for what might be more equitable but suggests further consideration of that threshold would be appropriate.

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One possibility could simply be to consider an amount that is halfway between the standard APC and the complexity-adjusted APC. In this example, the middle between APC 5193 for Level 3 Endovascular Procedures at \$10,602.57 and APC 5194 for Level 4 Endovascular Procedures at \$17,195.36 would be a threshold of \$13,898.97 rather than double the comparison low cost HCPCS code 36905 at \$16,213.52. This would still not adjust the codes about which we are concerned but given the aforementioned concerns about low-volume uptake here, it could be a start once the apparent underreporting of codes and/or costs is remedied.

Expiration of Transitional Pass-Through for Coronary IVL on June 30, 2024

Looking forward to avoid obstacles to cardiovascular care in the future, the College is aware that the Transitional Pass-Through (TPT) Payment Status for coronary intravascular lithotripsy (IVL) will expire on June 30, 2024. This will create a hospital reimbursement gap of at least six months, given TPT will not apply from July 1-December 31, 2024. The College is concerned that this gap in reimbursement could negatively affect Medicare beneficiary access as no additional payment will be issued while hospitals will continue to incur additional costs of coronary IVL when utilized.

In the hospital inpatient setting CMS recently finalized policy to address potential reimbursement issues by creating distinct MS-DRGs that reflect the total costs of hospital discharges when coronary IVL is utilized. Similarly, we request that CMS address this gap in reimbursement so that it does not restrict Medicare beneficiary access or influence clinical settings of care during the six months in question. That could be done by terminating the TPT such that it expires December 31, 2023 and then applying the standard complexity adjustment policy for PCI utilizing IVL beginning January 1, 2024, by applying the standard complexity adjustment policy on July 1, 2024 when TPT ends, or perhaps some other solution CMS might envision. **The College urges CMS to adopt some solution regarding the mid-year expiration of the TPT for IVL.**

Supervision by Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services Furnished to Outpatients

CMS proposes updates to implement portions the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123) that revise the definitions of the cardiac rehabilitation (CR) program and intensive cardiac rehabilitation (ICR) program, respectively, to provide that services these programs furnish can be under the supervision of a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) beginning January 1, 2024. Before that effective date of these amendments, only physicians could supervise services furnished as part of CR and ICR programs. **The ACC supports the proposed conforming revisions to § 410.27 that implement this important change that will remove a barrier to optimal cardiovascular care.**

Noting the extension of various telehealth flexibilities that were extended in the Consolidated Appropriations Act of 2023 through the end of CY 2024, the Agency also proposes to align regulations in § 410.27 to allow for the direct supervision of CR and ICR to include the virtual presence of the physician through audio-video real-time communications technology (excluding

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audio-only) through December 31, 2024 and extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024. CMS further seeks comments on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the current or proposed extensions and what policies CMS could adopt to address those concerns if the policy were extended beyond 2023. **The ACC supports the proposed extension of virtual presence flexibility through 2024, and its applicability to all clinicians eligible to supervise these services in 2024.**

Regarding safety and/or quality of care concerns, the ACC and other societies active in the cardiac rehabilitation space have previously provided literature on the absence of safety issues when care is provided in this manner and urged this policy be made permanent. The ACC is prepared to provide additional information along those lines that could be further considered for 2025 rulemaking.

Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital

To correct an inconsistency made when the broad policy to implement Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) (BBA, 2015) was created, CMS proposes to no longer apply the 40-percent adjustment to the OPPS rate for ICR services provided at off-campus, non-excepted PBDs. The ACC agrees the rates and policy as they currently stand do create an unintended payment disparity at the PBDs and supports the change to exclude ICR from the 40-percent Relativity Adjuster policy at the code level for HCPCS codes G0422 and G0423.

Additional instances of such an inconsistency are also solicited by CMS. While cardiac rehabilitation (CR) services were not included in the original Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) statute that directs coverage and payment of ICR, they are clinically very similar to ICR services and are also underutilized services with a proven record of improving patient quality of life and rehospitalization outcomes. **It would be appropriate for CMS to also exclude CPT codes 93797 and 93798 from the 40-percent Relativity Adjuster policy at the code level for services provided at off-campus, non-excepted PBDs.**

OPPS Payment for Dental Services

CMS proposes to assign 229 dental codes for various services to clinical APCs for payment starting in 2024. The ACC is not able to offer comment on the appropriateness of those services each meeting the requirements CMS outlined during CY 2023 rulemaking. However, the ACC appreciates CMS's thoughtfulness in considering these updates to its payment rules for dental care. It is well established that chronic diseases disproportionately impact Medicare beneficiaries and impose a substantial cost on the federal government. It is also well established that untreated oral microbial infections are closely linked to a wide range of costly chronic conditions, including diabetes, heart disease, dementia, and stroke. In addition, oral diseases have been documented by researchers and medical specialty societies as precluding, delaying, and even jeopardizing medical treatments such as organ and stem cell transplantation, heart valve repair or replacement, cancer chemotherapies, placement of orthopedic prostheses, and management of autoimmune diseases.

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The ACC generally supports CMS’s proposed treatment of dental care in this rule, finding it consistent with relevant guidelines to assess and remediate oral health issues before valve procedures. Dental infections and poor oral health increase the risk of infection in a newly implanted heart valve. Patients can have primary bacterial endocarditis or, worse, prosthetic valve endocarditis secondary to neglected dental health and chronic dental abscesses. These are life-threatening situations that could be prevented with payment for medically necessary oral/dental health therapies. At the same time, while the ACC believes that targeted access for dental services related to specific conditions will improve outcomes, CMS should proceed cautiously and be guided by strong evidence regarding when to conserve scarce resources as it considers additional services in the future under the newly proposed process, which seems appropriate at this juncture. In regard to the assignment of dental codes to clinical APCs, the ACC urges diligent monitoring of the impacts these assignments have on APCs. It is possible that additional action will be appropriate when cost data for these procedures begins to be available.

Proposal to Modify the Requirements for Making Public Hospital Standard Charges

Building on prior rule making, CMS proposes updates and enhancements to its Hospital Price Transparency rules with the intent of encouraging a patient-driven health care system where informed patients are empowered to know standard charges for hospital services. CMS proposes changes to the specific charge information and display requirements, as well as new actions the Agency may take and that hospitals must take to further compliance.

While supportive of the power of transparency to inform the public, the ACC expressed concerns in CY 2020 rulemaking about the difficulty of patients effectively utilizing machine readable format data to guide care in ways that consider factors other than cost, and the possibility that such a program of transparency could have the unintended consequence of reducing competition. At that time, the College suggested a pilot program or a phased-in implementation prior to full implementation of a broad transparency program.

With those prior caveats in mind, it is apparent the Agency has heard constructively critical feedback from stakeholders in the intervening years, including from the HHS Health Federally Funded Research and Development Center technical expert panel. Updates to the initial program are needed to reduce burdens to disclosure by facilities with greater specificity on data fields and the availability of data templates, encourage compliance with the creation of additional punitive actions, and to create context that can improve the public’s ability to understand and use hospital standard charges. With the changes proposed, it appears the Agency is addressing some of the ACC’s prior concerns with the benefit of hindsight. The ACC generally agrees with the proposed updates as a means of improving the existing hospital price transparency program to make it more manageable for hospitals and more meaningful for patients and the public. The ACC continues to believe transparency in health care decision making—including pricing of services—plays an important role in providing patients, clinicians, and policy makers the necessary context to optimize care.

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Comment Solicitation on Potential Issues Caused by Current Payment of Diagnostic Radiopharmaceuticals Under the OPPTS

OPPTS policy packages several categories of non-pass-through biologicals and radiopharmaceuticals regardless of the cost of the products. These “policy-packaged” drugs, biologicals, and radiopharmaceuticals function as supplies when used in a diagnostic test or procedure and is packaged with the payment for the related procedure or service. CMS packaged diagnostic radiopharmaceuticals in CY 2008 rulemaking and some stakeholders have raised concerns regarding the insufficiency of payment rates after pass-through status expires, especially for high-cost radiopharmaceuticals with low utilization.

CMS requests feedback on how its policy of policy-packaged radiopharmaceuticals has impacted beneficiary access and whether there are specific patient populations or clinical disease states for which this issue has been especially problematic. In particular, CMS is interested in feedback on five approaches that could enhance beneficiary access to certain radiopharmaceuticals while maintaining the principles of the outpatient prospective payment system:

1. Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPTS drug packaging threshold of \$140
2. Establishing a specific per-day cost threshold that may be greater or less than the OPPTS drug packaging threshold
3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals
4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials
5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

The ACC recognizes that packaging policy for precision diagnostics radiopharmaceuticals in the outpatient setting can create barriers to beneficiary access particularly, in the case of high-cost, low-volume radiopharmaceuticals deployed for certain clinical disease states. Separate payment for radiopharmaceuticals over a certain per-day cost threshold may be a reasonable solution to address that issue. Mechanisms to address poor source hospital charge and cost data should be implemented in tandem to mitigate unintended impact.

However, to lend robust support to a particular per-day cost threshold it is imperative that interested stakeholders understand the specific impact on nuclear medicine APCs that would result from such a change in policy. Separate payment for currently packaged radiopharmaceuticals would necessarily decrease nuclear medicine APC payment rates. In the case of high-cost radiopharmaceuticals it is predicted that any decrease to the resulting nuclear medicine APCs would be paired with an increase for a separately paid radiopharmaceutical. However, it is less clear that the same would be true for radiopharmaceuticals with costs only slightly above the OPPTS drug packaging threshold. For instance, Rb-82 Rubidium has a 2022 per day geometric mean cost of \$232.14. It would be separately paid if CMS sets the threshold at the OPPTS drug packaging threshold at \$140 but stays packaged if a higher threshold is set.

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Furthermore, valuations of per-patient dosing for generator-based radiopharmaceuticals like Rb-82 are complex because each dose is tailored and calibrated for the needs of the particular patient (weight-based dosing in some instances). Rb-82's short physical half-life of 75 seconds means each dose uses an elution system to deliver weight-based patient dosing. The number of doses a single generator will provide is not static and may differ based on the patient population and the number of patients tested daily in each laboratory. Thus, the cost of the radiopharmaceutical can vary month to month. To understand the full impact on cardiac PET and PET/CT services that use Rb-82, both the impact on the nuclear medicine APCs and the pricing methodology for separate payment would need to be discussed in greater detail.

CMS discusses that separate payment for radiopharmaceuticals over a certain cost threshold would be determined by “available average sales price (ASP), wholesale acquisition cost, or average wholesale price (AWP) data with the applicable add-on.” However, unlike drug manufacturers, radiopharmaceutical manufacturers are not currently required to submit data on average sales price and any submissions would be voluntary. Transparency and clarity around how separately paid drugs are reimbursed is essential. Different resources should be available to develop pricing methodology in different venues to ensure adequate patient access.

ACC understands the desire to consider the option to recognize radiopharmaceuticals as unique drugs that require accurate reimbursement to ensure beneficiary access to critical treatment. However, given the complexities of hospital cost data and issues with insufficient hospital reporting on costs in packaged situations, we are concerned about unknown impacts of full implementation of a policy to separately pay for radiopharmaceuticals. Adequate information is not available to the ACC to make a clear recommendation on a per-day cost threshold at this time. We urge CMS to continue engagement with stakeholders to develop a policy that will account for complexities unique to generator isotopes, ensure accurate data collection and utilization, and generate ongoing modeling to monitor for unintended consequences.

Proposed Measures for Inclusion

Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) Measure

The ACC is generally supportive of any measure that provides a standardized method for oversight of the performance of diagnostic CT by monitoring the use of high radiation doses (a risk factor for cancer) while preserving image quality. However, the ACC does have concerns regarding this particular metric for consideration by CMS. Measure stewardship is in collaboration with the University of California San Francisco (UCSF). UCSF created Alara Imaging to develop the eQCM software and support measure stewardship. While there is presently no cost to use the software, CMS should consider the implications of adopting a measure that relies upon use of a proprietary system. Hospitals and health systems will face an additional burden in implementing the proprietary program and ensuring compatibility within their system IT networks. As the software requires access to hospital or health system electronic health records to calculate the variables necessary for completing the measure, the potential for information system vulnerability (i.e., cybercrime) warrants

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consideration.

Further, concern has been expressed through the consensus process regarding the current level of consensus as to what constitutes “excess radiation dose”. Endorsed national benchmarks are lacking. Patient-centered care should encompass appropriate imaging – the right test for the right patient. This means that at times a higher radiation dose will provide greater test accuracy, and that trade-off may be entirely appropriate for a particular patient. Test substitution may result (e.g., stress echocardiography for stress nuclear perfusion imaging) solely for the purpose of metric performance rather than proceeding forward with what might be the better test for a particular patient. Additional potential unintended consequences should be monitored over time, such as the inappropriate shifting of care or coding/billing practices, or increased patient morbidity and mortality.

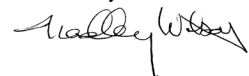
Surgical Volume Measure

CMS notes that given the notable shift in procedures from inpatient to outpatient settings, it believes tracking outpatient procedural volume will help inform patients about a given facility’s experience with outpatient procedures. We continue to caution CMS that surgical volume is not an indicator of quality and could encourage the use of inappropriate interventions. Also, patients have diverse preferences and values when making healthcare decisions. While some may place great importance on the implications of surgical volume (e.g., expertise), others may prioritize different aspects of care. Some patients may prioritize factors such as the quality of communication with the surgeon, personalized treatment plans, and the overall care experience over surgical volume. In addition, for rare or complex procedures, surgical volume data may be less relevant as there might be limited options available, and the focus might shift more towards the surgeon's expertise in that specific field. Accessibility and proximity to a healthcare facility might be more critical for certain patients, especially if they live in remote areas or face challenges in traveling long distances. Other considerations include cost, insurance coverage, post-operative care, and the reputation of the healthcare facility or surgeon.

Conclusion

Thank you for your consideration of these comments from the ACC. The College appreciates the thought and effort that go into rulemaking and looks forward to future engagement on topics included in this and other rules and policy discussions. Please contact Matthew Minnella, Associate Director, Medicare Payment Policy at mminnella@acc.org if additional information would be helpful.

Sincerely,



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