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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.

September 1, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
200 Independence Ave. SW
Washington, DC 20201

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018 [CMS-1676-P]

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the CY 2018 Physician Fee Schedule (PFS) and other policies addressed in this proposed rule.

The ACC is the professional home for the entire cardiovascular care team. The mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, offers cardiovascular accreditation to hospitals and institutions provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

In this letter, the College specifically addresses the following areas:

- Implementation of and changes to the Appropriate Use Criteria Program
- Changes to malpractice and practice expense components of the fee schedule
- Recommendations regarding work relative value units for specific codes
- Payment rates for services provided by Off-Campus Provider-Based Departments
- Quality and value program adjustments and reporting
- Patient relationship codes to be used in quality reporting

Appropriate Use Criteria Program (AUC Program)

Consultation by Ordering Professional and Reporting by Furnishing Professional

The ACC supports the proposal to implement the AUC consulting and reporting requirement for ordering professionals on January 1, 2019, rather than the current date of January 1, 2018. The College is committed to developing, updating, and promoting the use of appropriate use criteria (AUC) in clinical decision-making to improve patient care and health outcomes in a cost-effective manner and to reduce excessively burdensome pre-authorization processes. However, a mandatory program such as the AUC Program should *only be implemented* once CMS can ensure readiness among the clinicians, billing staff, vendors, and other stakeholders impacted by this program. The ACC is pleased that CMS proposes the one-year implementation delay to 2019 in order to educate and collect additional feedback from the public, to provide clinicians with time to implement systems within their clinical workflow, and to ensure that CMS' own claims processing systems are prepared for the program.

While the ACC supports using 2019 as an education and operations testing period, the College opposes CMS' expectation not to continue education and testing beyond the first year of the AUC program. Consultation with AUC through a CDSM will be a new practice for many clinicians. As the program continues, new clinicians will enter the program and new AUC, EHRs, and CDSMs will be developed. This flux will undoubtedly cause new questions and the need to ensure that new systems are capturing the appropriate information. **Rather than end education and testing at the end of the first year, the ACC urges CMS to continue education through guidance and programs and to allow for operations testing as clinicians move between CDSM and EHR systems.**

The College supports re-evaluation of the program start date during the 2019 PFS rulemaking cycle. At this time, a one-year delay provides clinicians with time to select a CDSM vendor, become familiar with AUC consultation, and begin the process of submitting claims with the information required for the program. **CMS should not implement the AUC consulting and reporting requirement until clinicians have had time to complete these steps and CMS has had the opportunity to provide clinicians with initial feedback confirming that claims have been submitted according to program requirements during the test year. If claims are not being submitted correctly, feedback should clearly indicate what must be done in order to comply with program requirements.**

Consultation with AUC encourages professionals who order imaging services to engage in conversation with those who furnish imaging services, working together to ensure that imaging services are appropriately provided to patients. Any education and feedback from CMS should be targeted at both ordering and furnishing professionals.

To assist CMS in determining the proper timing for implementation of the AUC program, the ACC recommends that the Agency ensure that the following factors are met prior to the collection of any data for outlier calculations:

- There are sufficient qualified CDSMs available to all practice settings, including the one free option required by statute, that allow clinicians to access their preferred AUC set without burdensome administrative, financial, or EHR integration barriers.
- CMS provides guidance around the process through which ordering clinicians must report AUC consultation as part of the claims process, including but not limited to specific reporting, certification and documentation requirements.
- CMS develops policy safeguards to ensure that program implementation does not result in the inappropriate underutilization of advanced imaging services to Medicare beneficiaries.
- Sufficient resources and software solutions are supplied by EHR vendors to clinicians, practices, and healthcare systems to integrate CDSMs without undue burden, especially to small practices.
- Regulations confirm that the determination of outlier clinicians for prior authorization purposes will be based on two years of data collected under the program, as required by statute.

While CMS has addressed some of these issues in rulemaking in this proposed rule and prior rules, these factors should continue to be addressed as part of ongoing implementation of the program.

HCPCS Level 3 Codes

Classification of "May be Appropriate Care"

CMS proposes to create a new series of HCPCS level 3 codes to describe the specific CDSM used by the ordering professional and additional modifiers to describe the applicability of the AUC and situations where an exception applies. The ACC recognizes that collecting this data through the use of HCPCS codes on the CMS claims form is the least administratively burdensome process for both clinicians and CMS; however, the College is concerned that the proposed codes and documentation processes are not entirely clear.

The College is particularly concerned that the modifiers describing the applicability of the AUC to an imaging service do not clearly indicate how "may be appropriate care" should be documented. In 2016, the American College of Cardiology Foundation (ACCF) was approved as a qualified provider-led entity (qPLE) to develop AUC for the program. Under the ACCF methodology, decisions are defined as one of the following three categories:[1]

Median Score 7 to 9: Appropriate Care
An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans although not always necessary, depending on physician judgment and patient specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).

Median Score 4 to 6: May be Appropriate Care
At times, an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefits/risks ratio, potential benefit based on practice

[1] Robert C. Hendel, Manesh R. Patel, Joseph M. Allen, James K. Min, Leslee J. Shaw, Michael J. Wolk, Pamela S. Douglas, Christopher M. Kramer, Raymond F. Stainback, Steven R. Bailey, John U. Doherty, Ralph G. Brindis Journal of the American College of Cardiology Mar 2013, 61 (12) 1305-1317; DOI: 10.1016/j.jacc.2013.01.025 (Available at: http://www.onlinejacc.org/content/61/12/1305).

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experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).

Median Score 1 to 3: Rarely Appropriate Care
Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

CMS proposes three HCPCS modifier categories of: "1) The imaging service would adhere to the applicable appropriate use criteria; (2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered." Based on these proposed categories, it is unclear how orders falling in the "May be Appropriate Care" range should be documented.

The Agency must confirm through the final rule or subregulatory guidance that any service rated as "may be appropriate" under the ACCF or other qPLE-developed AUC be documented using the modifier for category "1) the imaging service would adhere to applicable appropriate use criteria." This should also be communicated through education and outreach on the proper documentation of AUC results. As stated in the ACCF methodology, there may be times when services may be acceptable and reasonable for the indication based on individual patient factors, clinical variables, and clinician judgment in the absence of evidence and/or variability of the population. The ACC is concerned that placing these cases in either the "(2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered" HCPCS modifier categories could discourage utilization of tests for patients where there may be clinical benefit.

AUC Exceptions

CMS proposes to create additional HCPCS modifiers where an exception applies and a qualified CDSM was not used to consult AUC. These exceptions include imaging services ordered for a patient with an emergency condition or services where the ordering professional qualifies for a significant hardship exception. It is the College's understanding that clinicians ordering services under these scenarios would bypass AUC consultation through a CDSM due to either the time-sensitive nature of the patient's condition or the lack of technological infrastructure within a practice. However, based on the ACC's interpretation of the proposed rule, these modifiers would have to be reported with the G-code describing a CDSM mechanism used when there may not be one used. **The ACC recommends that CMS either create HCPCS codes rather than modifiers for exceptions or state that the modifiers should be applied to the service code.**

In addition to the two exceptions stated in the proposed rule, the ACC recommends that CMS provide guidance stating that "a patient with an emergency condition" includes those patients held under observation in a chest pain unit or other emergency observation unit. It is currently unclear whether only the initial imaging service provided to the patient under an emergency condition would

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fall under the exception, or if all imaging services provided under emergency department observation would be excepted.

Additional Considerations for Future Outlier Calculations

The College recognizes that CMS does not propose policies related to the identification of outliers in this proposed rule. However, as part of the consideration of the HCPCS codes used to document compliance with this program, the ACC requests that CMS begin to consider whether the proposed codes alone will be sufficient for the calculation of outliers. For instance, if only on the claim submitted by the furnishing professional, the HCPCS codes alone will not tell CMS who the ordering professional was. In cases where the ordering and furnishing professionals are different, the claim submitted by the furnishing professional must include the name and NPI of the ordering professional. CMS must be able to validate this information and factor it into its outlier calculation.

In addition, clinical evidence may evolve over the course of the AUC program. A scenario may arise where new clinical evidence suggests that services that had been rated as rarely appropriate or non-adherent to AUC may be appropriate for a particular patient indication or population. If the AUC are updated to reflect this change, then CMS' outlier calculation should also be updated to ensure that a clinician is not penalized for services that may in fact be appropriate based on the most recent clinical data. The new HCPCS codes alone will not capture this information.

When CMS calculates outliers, the Agency should take into account the patient indication attributed to each rated service, as well as other factors such as the geographic location and site of service. When possible, CMS should collect this data from information already collected on the CMS claims form to minimize the reporting burden prior to considering the creation of new HCPCS codes. CMS should work with qualified CDSMs to determine how to collect additional information that may be captured through the mechanisms, but not the claims form.

Alignment with Other Medicare Quality Programs

The ACC strongly supports participation in the Appropriate Use Criteria (AUC) program for advanced imaging services created under the Protecting Access to Medicare Act of 2014 (PAMA) as a high weight Improvement Activity (IA) for Merit-based Incentive Payment System (MIPS) credit in 2018. The ACC sees significant value in AUC consultation over prior authorization to reduce the ordering of potentially inappropriate services. The College appreciates the credit awarded to early adopters of the program as several practices and facilities have already taken steps to implement AUC and clinical decision support (CDS) consultation in anticipation of a January 1, 2018 start date. This program will require many ordering clinicians to consult with AUC and CDS mechanisms for the first time and will promote a new level of care coordination between clinicians ordering and furnishing advanced imaging services.

CMS should maintain participation in the AUC program as a high weight activity not only for the 2018 performance period, but also for future years. In addition, the College looks forward to working with CMS to determine how the goals of the AUC Program can further align across all MIPS categories and alternative payment models under the QPP.

The ACC is pleased that CMS is considering how the AUC program can serve to support a quality measure under MIPS and supports further consideration of how the goals of the AUC program can be achieved as part of MIPS or alternative payment model participation.

The ACC currently has three appropriate use measures for cardiac imaging that are currently available for MIPS reporting:

- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low Risk Surgery Patients (MIPS 322)
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI) (MIPS 323)
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients (MIPS 324)

Clinicians participating in the AUC program should be encouraged to report these high-priority measures as part of their MIPS participation.

Significant Hardship Exceptions to Consulting and Reporting Requirements

The ACC supports alignment of significant hardship exceptions to consulting and reporting requirements for clinicians who also qualify for exceptions under the Advancing Care Information category of MIPS. The efficient use of CDSM depends greatly on the availability of Internet and CEHRT. Implementing the AUC program by January 1, 2019 will be most burdensome to clinicians who do not have access to this connectivity; therefore, the ACC support exceptions for these clinicians.

Unintended Consequences of the AUC Program

The ACC asks that CMS continue to work with stakeholders to identify potential unintended consequences of this program. Most importantly, CMS should ensure that the AUC program does not result in barriers to delivering timely and appropriate patient care. Through further alignment with MIPS and alternative payment models, CMS can find ways to measure the quality of care provided under the program and ensure that quality outcomes do not decline due to changes in practice under the program. CMS should also ensure that the process for identifying outliers in future years does not result in clinicians unintentionally being flagged for prior authorization due to their patient demographics or other factors where imaging may be appropriate.

Malpractice (MP) RVUs

The ACC opposes CMS's proposal to apply a single, blended risk factor to both surgical and non-surgical services performed by cardiologists. CMS proposes revisions to MP RVUs based on updated malpractice premium data obtained by state insurance rate filings by a contractor. Such an update of premium data is required at least every 5 years, and was most recently completed for CY 2015. The CY 2018 review and proposed changes are methodologically similar to the CY 2015 update, which was similar to the 2010 update before that.

For reasons not specified in the contractor's report or in the proposed rule, data were not available from the 35 states required by the methodology to establish a separate surgical risk factor for the cardiology specialty. As such, the contractor and CMS propose to use a blended MP risk factor that would apply to both non-surgical and surgical procedures. This change reduces the surgical MP factor for cardiology by about 73%, from 6.98 to 1.90. This would inexplicably apply a lower surgical risk factor to procedures performed in and on the heart by cardiologists than to procedures performed elsewhere in the body by other specialties. **The ACC opposes this change and recommends CMS apply a crosswalk from the cardiac surgery risk factor of 6.87 to the cardiology surgical risk factor.** This would appropriately differentiate the more than three-fold difference that exists in premiums between an office-based cardiologist who manages patients medically and interprets cardiovascular imaging and an interventional or electrophysiologic cardiologist who performs risky procedures in/on the heart.

As mentioned in the proposed rule, MP represents only about 4.3% of payment in the fee schedule. Table 5.2 in the contractor's report predicts the impact of the change to result in a 25.3-percent reduction to cardiology MP RVUs and a 1.1-percent reduction in total RVUs. These changes may seem modest at scale, but at the individual service level they would create significant harm, as shown using a few examples in the below table with codes that had no changes to work or PE factors.

Code	**Descriptor**	**2017 MP RVU**	**2018 MP RVU**	**2017 Payment**	**2018 Payment**	**Reduction**
33208	Insert heart PM atrial & ven	1.97	0.64	$543.35	$497.03	-8.5%
92941	Revascularization during AMI	2.83	0.81	$695.52	$624.79	-10.2%
92580	Transcath closure of asd	3.95	1.23	$1021.75	$926.72	-9.3%
93458	L hrt artery/ventricle angio	1.12	0.18	$310.44	$277.49	-10.6%

Practicing physicians should not see payment reduced in this manner because of an administrative shortcoming. During the 2015 update, CMS's contractor collected data regarding major surgery premiums for cardiologists in 41 states. Three years later CMS's contractor was only able to collect data in 12 states. The ACC urges CMS and the contractor to work with ACC and other societies to better understand the data it does have and to identify new sources that may be useful in improving this flawed dataset. One suggestion is to engage directly with insurers to obtain premium information to supplement or crosscheck data obtained from state departments of insurance.

Finally, CMS has consistently applied a surgical risk factor to invasive cardiology procedures that are outside the surgical HCPCS code range, stating "We continue to believe that the malpractice risk for cardiac catheterization and angioplasty services are more similar to the risk of surgical procedures than to most nonsurgical service codes." The same rationale should now be applied to both invasive cardiology procedures outside the surgical code range as well as in the code range—a significant difference exists for these services that must be incorporated into a relativity-based payment system.

Practice Expense (PE) Relative Value Units (RVUs)

0- and 10-day Global Preservice Time

After a brief discussion regarding the practice of some 0- and 10-day global procedures including recommendations for clinical staff preservice time as part of a service's direct practice expense, CMS requests comments on whether the standard preservice clinical labor time of 0 minutes should be consistently applied for these codes in future rulemaking. CMS notes the RUC has previously agreed that no preservice clinical staff time is included for these services unless a compelling reason exists to deviate from the standard. **The ACC cautions CMS against eliminating clinical staff preservice time from all 0- and 10-day global procedures in future rulemaking.**

A few nuances should be considered in any change CMS considers. Historically, many of these procedures would be of a more minor nature and may have been performed the same day a patient presented with a complaint. However, many of these procedures also correctly include clinical preservice time to allow for facility scheduling, patient coordination, and other activities. Additionally, in the past decade several complex procedures were implemented as 0-day procedures to allow flexibility for multiple clinicians on the care team to care for a patient without being limited by a 90-day global period. Another consideration is that while the Agency may view deviation from the "standard" as a potential problem, in fact, it is functioning as it should—the expectation is 0 minutes for these services unless a compelling reason exists to include time for activities like those mentioned above. Not all 0- and 10-day services are equal in this manner. Rather than making a blunt and counterproductive change, the ACC suggests CMS engage societies and the RUC to explore whether this deviation from the standard is a concern and, if so, how to efficiently review the topic.

Obtain Vital Signs Clinical Labor

CMS proposes to apply 5 minutes of clinical labor time for all codes that include at least 1 minute assigned to the clinical staff task of "Obtain vital signs." The corresponding equipment times would be adjusted accordingly to align with this proposal. CMS notes this change would ensure relativity, as it has observed codes reviewed more recently to include higher amounts of time for this clinical task, reflecting either changes in medical practice or review standards or both. While the ACC agrees this variance may warrant some scrutiny, it goes too far in standardizing inputs. Differences do exist between services and the fee schedule is meant to account for them.

Telehealth Services

Remote Patient Monitoring

Separate payment for remote patient monitoring services that do not fit the statutory definition of telehealth services may create new opportunities to enhance patients' access to care. This topic is increasingly important as apps and wearable devices evolve to collect and transmit data and information that physicians can interpret and incorporate into patient care workflows. The ACC applauds CMS for pursuing feedback on this issue. CMS notes one CPT code, 99091, that describes interpretation and review of physiologic data as one opportunity. This code was first published in 2002. While it may reasonably approximate the sort of remote monitoring in which CMS is interested, the ACC suggests technologic changes in the ensuing years would warrant a broader reconsideration of this topic rather than relying on one code to capture the many iterations of remote patient monitoring that now exist. Consideration by stakeholders at a forum such as the CPT Editorial Panel would also allow discussion about billing processes and patients' informed consent.

In fact, two relevant telehealth proposals are scheduled to be discussed at the upcoming CPT Editorial Panel meeting.

Valuation of Specific Codes

For CY 2018, CMS has generally proposed values recommended by the American Medical Association Relativity Value Scale Update Committee (RUC). The ACC participates in that process and supports the decision to rely upon the RUC's rigorous and thorough process.

Cardiac Electrophysiology (EP) Device Monitoring Services

CMS identified several services in this family as potentially misvalued through a high expenditure screen during CY 2016 rulemaking. Based on the codes flagged by CMS, the ACC and the Heart Rhythm Society undertook review of this large family of codes through the RUC process. **The ACC supports CMS's proposal to adopt the work RVUs recommended by the RUC.** CMS also discussed alternative RVUs for several codes upon which it sought comment. Additional thoughts on each of those codes is provided for further consideration.

93283: (CMS wrote "93293" in the proposed rule, but cited a 25th-percentile survey result as a consideration which aligns with 93283. These comments follow accordingly, assuming an understandable typo.) CMS questioned whether 93283 should have a work RVU of 0.91, the survey 25th-percentile value, to better maintain relativity between single- and dual-lead pacemaker systems and cardioverter defibrillator services. That option would underrepresent the increment between single- and dual-lead cardioverter defibrillator services, creating an increment of 0.06 between the two cardioverter codes while an increment of 0.12 exists between the two pacemaker codes. The recommended increment of 0.30 better represents the increased work of programming a dual-lead cardioverter defibrillator. The comparison between pacemakers and cardioverter defibrillators is not 1:1 or 1:2, but in general, cardioverter defibrillator services warrant more work due to hardware, software, and complexity considerations. The ACC supports the RUC-recommended value of 1.15 that CMS proposed.

93282: An alternative RVU of 0.74 was offered, again to align relativity between single- and dual-lead pacemaker and cardioverter defibrillator systems. No crosswalk or survey link was offered, so it is not clear how this value was identified as a potential alternative. It is also not clear whether this would be in addition to the alternative for 93283 or in lieu of that change. Assuming the former, this would create an increment of 0.15 between the two cardioverter defibrillator services. As above, the recommended increment of 0.30 better represents the increased work of programming a dual-lead cardioverter defibrillator. Additionally, by lowering the single-lead cardioverter defibrillator code, CMS is creating other relativity problems by making 93282 close in value to 93279. Survey respondents clearly indicated 93282 is more work than both 93279 and 93280. This relativity is also important. The ACC supports the RUC-recommended value of 0.85 that CMS proposed.

93289: Noting an increment of 0.10 between 93282 and 93289 at the RUC-recommended values, CMS considered whether a value of 0.69 would be preferable to create a proportionate reduction to align with the reduction considered to 93282. However, such a reduction is not relevant if CMS finalizes the proposed, RUC-recommended value for 93282. The ACC supports the RUC-recommended value of 0.75 for 93289 that CMS proposed.

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93293: This is the first of several codes for remote monitoring of cardiac devices that includes multiple transmissions and interpretations over a period of time. The current times and values for these codes are a combination of crosswalks and/or multiplying times and values from related or similar services by an assumed number of transmissions per period. The recommendations describing these calculations were submitted by the RUC in May 2008. Those calculations produced some artificially long times, and ACC and the RUC believe the mostly survey-based recommendations are an improvement over the current calculated times. CMS questions whether a crosswalk to a value of 0.26 from a service with comparable time would be appropriate, noting that the total time for 93293 decreased 7 minutes but resulted in only a 0.01 reduction. The 0.31 recommendation is the survey 25th-percentile result. It also aligns with another cardiology service, 93018 for stress test interpretation and report, that has 0.30 RVUs, the same 5 minutes of intraservice time, and two minutes less total time. The valid survey and the comparison code support the value of 0.31. The ACC supports the RUC-recommended value of 0.31 that CMS proposed.

93294: CMS posits a 0.05 reduction in value to 0.55 for this code using a crosswalk to 76706 that has 10 minutes intraservice time and 20 minutes total time. The 0.60 recommendation is the survey 25th-percentile value. It also aligns with two codes provided to CMS in the RUC submission—76815 and 69210 that have values of 0.65 and 0.61, respectively. The valid survey and the comparisons support the value of 0.60. The ACC supports the RUC-recommended value of 0.60 that CMS proposed.

93295: CMS considers a 0.05 reduction in value to 0.69 for this code using a crosswalk to 76586 that has identical times to 93295 of 10 minutes intraservice and 20 minutes total time, noting the reduction in times. The 0.74 value already accounts for that reduction in time. It aligns relatively with services provided to CMS in the RUC submission—93224, 99213, and 78306 that have times and values above and below the recommendation. A value of 0.69 would also anomalously place 93295 further below its in-person equivalent, 93289; at under the proposal, the codes are nearly identical at 0.74 and 0.75. The ACC supports the RUC-recommended value of 0.74 that CMS proposed.

93298: Again noting the reduction in times from extrapolated values and concerns that the resulting work RVU does not adequately reflect that reduction, CMS discusses a 0.15 reduction in value to 0.37 for this code using a crosswalk to 96446 that has identical times to 93298 of 7 minutes intraservice and 17 minutes total time. The 0.52 value aligns relatively with services provided to CMS in the RUC submission—93224, 76536, 76857, and 92136. It is also the survey 25th-percentile value. The ACC supports the RUC-recommended value of 0.52 that CMS proposed. Maintaining this value also eliminates the need to make any parallel adjustment to 93297, as CMS mentioned.

The ACC worked with the RUC to respond to PE revisions proposed by CMS, and supports the submission that resulted from that coordinated effort.

Transthoracic Echocardiography (TTE)

CMS identified TTE code 93306 as potentially misvalued through a high expenditure screen during CY 2016 rulemaking. The ACC and American Society of Echocardiography undertook review of the family of codes through the RUC process. **The ACC supports CMS's proposal to adopt the work**

RVUs recommended by the RUC. CMS also discussed alternative RVUs for several codes upon which it sought comment. Additional thoughts on each of those codes are provided for further consideration.

93306: Review of 93306 identified compelling evidence that a change in technique and technology produced a change in the work of 93306. Physicians review more images in the same amount of time and perform additional testing such as diastolic function and spectral tracking that did not occur 10 years ago. CMS considered whether to maintain the existing work RVU of 1.30, noting the 1.5-minute reduction in post-service time. Consistent with the 25th-percentile value of 1.50 from a robust survey and an understanding of the increased work inherent in this service when compared to a decade earlier, the ACC supports the RUC-recommended value of 1.50 that CMS proposed.

93307: CMS notes a 3-minute drop in service time for 93307 as a reason to consider a work RVU of 0.80, crosswalked from services with similar times. The recommendation of 0.92 is already below the 25th-percentile survey value and compares well with services CMS did not mention—76805 and 95819—that have higher values and identical intraservice times. The ACC supports the RUC-recommended value of 0.92 that CMS proposed.

93308: CMS considered a work RVU of 0.43, crosswalked from 93282 because of the similar service times as it noted a reduction of 5 minutes in time for 93308 that did not produce a reduced work RVU recommendation. The recommendation of 0.53 is already below the 25th-percentile value and compares favorably with codes of identical times and similar RVUs—78014, 93882, 93979. The ACC supports the RUC-recommended value of 0.53 that CMS proposed.

No PE refinements were proposed for these codes. The ACC supports the proposal to adopt the RUC-recommended direct PE inputs.

Stress TTE

CMS identified 93351 as potentially misvalued through a high expenditure screen during CY 2016 rulemaking. The ACC and American Society of Echocardiography undertook review of the family of codes through the RUC process. **The ACC supports CMS's proposal to adopt work RVUs of 1.46 for 93350 and 1.75 for 93351 as recommended by the RUC and supported by a robust survey.**

The ACC worked with the RUC to respond to PE revisions proposed by CMS, and supports the submission that resulted from that coordinated effort.

Peripheral Artery Disease (PAD) Rehabilitation

A new national coverage determination (NCD) established Medicare coverage of supervised exercise therapy (SET) for the treatment of beneficiaries with peripheral artery disease with intermittent claudication. The ACC was engaged in that effort and is pleased to see CMS moving forward with the logistics of coding and payment. CMS indicates that existing code 93668 for SET will be payable by the end of CY 2017, retroactive to the NCD effective date. For CY 2018, CMS proposes the most recent RUC-recommended work and direct PE inputs. **This is a good starting point and the ACC supports this approach for CY 2018.**

CMS also seeks input on coding structure and valuation going forward. The ACC and other stakeholder societies have already begun working through the RUC process to evaluate coding structure and valuation assumptions. That forthcoming effort may or may not entail creation of new codes or coding instruction by CPT. ACC agrees that the current CPT coding instructions correctly prescribe that "the development of new arrhythmias, symptoms that might suggest angina or the continued inability of the patient to progress to an adequate level of exercise may require review and examination of the patient by a physician…These services would be separately reported with an appropriate level E/M service code…" Such work would not overlap with the patient's SET.

Finally, while atypical, individual session of SET does not currently include physician work, SET programs do require the overall medical direction of a physician. This aspect will also be considered as discussion occurs at the RUC. A coding solution may be the result of those efforts.

International Normalized Ratio (INR) Monitoring

A 2015 RUC screen of services with high utilization increases between 2008 and 2013 identified code G0250 for review, interpretation, and management of four home INR tests. The ACC sought referral of G0250 and related codes G0248 and G0249 to the CPT Editorial Panel to create CPT Category I codes to report this work. The result is codes 993X1 to report the PE of home INR training for the initiation of home INR monitoring and 993X2 for the anticoagulation management of patients taking warfarin regardless of where the lab test is performed. Existing anticoagulation management codes 99363 and 99364 which CMS has designated as bundled services are deleted in CPT 2018. **The ACC supports CMS's proposal to adopt the work RVU of 0.18 for 993X2 as recommended by the RUC.** Code 993X1 has no physician work.

CMS proposes to maintain G0248 and G0250 since they are "used to report services under a national coverage determination". This is unnecessary as the new codes were created to be consistent with the NCD governing coverage for home INR monitoring. 993X1 essentially mimics training code G0248. 993X2 is designed to supplant G0250, allowing physicians to report each management interaction as it occurs. NCD 190.11 states "self-testing with the device should not occur more frequently than once a week." Nothing in the NCD requires construction of a code in the style of G0250 that mentions specific clinical aspects or bundles management into bundles of four test interpretations. **CMS should reconsider the decision to maintain G0248 and G0250 and instead remove these two codes from the physician fee schedule.** G0249 should be maintained since the CPT Editorial Panel did not create a supply code to replicate it. The presence of these codes will be confusing for clinicians and coders since they are equivalent to 993X1 and 993X2. If this does not occur, additional guidance will be necessary so it is clear when the G codes are intended to be used and when the CPT codes.

The ACC worked with the RUC to respond to PE revisions proposed by CMS, and supports the submission that resulted from that coordinated effort.

Evaluation & Management (E/M) Guidelines

The ACC commends CMS on the proposal to makes changes to the E/M guidelines specific to the history and physical exam. Clinicians and other stakeholders agree that removing the

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documentation requirements for the history and physical exam would be a good initial approach to alleviate the burden of documentation.

The ACC believes that the criteria for documenting the history and physical exam portion of the E/M are significantly outdated with expansion of electronic health records (EHRs). The requirements set forth in the '95 and '97 guidelines were always found to be burdensome for the clinician. CMS seeks comment on whether it would be appropriate to remove documentation requirements for the history and physical exam for all E/M visits at all levels; the ACC agrees that the guidelines should be changed for all levels of E/M visits. Documentation should reflect what is communicated with the patient at each visit for all levels of E/M. Documentation should include why the patient is being seen, what was reviewed and noted, and all other communication to the patient during the visit. The ACC agrees with the comment that CMS should leave the degree of performance and documentation of the history and physical exam to the discretion of individual practitioners (specialty and primary care practitioners).

Currently, medical decision-making is based on quantifying diagnoses, management options, data, and risk. This leaves a certain amount of uncertainty for both clinicians and auditors. For example, there is no guidance regarding how the levels (minimal, limited, multiple and extensive) are applied when reviewing data. Streamlining this information with specific criteria that is easily understood by clinicians and auditors would help.

The ACC suggests that CMS work on revising the E/M guidelines with the AMA and the CPT Editorial Panel, as well as medical societies and all professional stakeholders (e.g., AHIMA, AAPC, etc.,).

Services Furnished by Nonexcepted Off-Campus Provider-Based Departments (PBDs) of a Hospital

Implementation of Section 603 of the Bipartisan Budget Act of 2015 requires certain items and services furnished by certain PBDs may not be paid under the hospital outpatient prospective payment system (OPPS). Payment for these services must be made under the "applicable payment system." For CY 2017, CMS implemented a payment system that scaled the OPPS payment rate downward by 50 percent, reducing the technical component of these services by a "PFS Relativity Adjuster." The PFS Relativity Adjuster percentage was selected after CMS analyzed OPPS PBD claims data from 2016 for 22 major codes and concluded that the weighted average of those codes demonstrated the PFS payment rate to be 45% of the OPPS payment rate.

For CY 2018, CMS indicates it does not have more precise data upon which it could propose an updated PFS Relativity Adjuster. Such data will not be available until after CY 2017. Despite that shortcoming, CMS notes ongoing concern that the CY 2017 PFS Relativity Adjuster of 50 percent "might be too small" and proposes to lower the PFS Relativity Adjuster to be 25 percent of the OPPS payment rate after analyzing the ratio between hospital outpatient clinic visit G0463 in comparison to the payment rates for the weighted average of office outpatient visits. The Agency also seeks comments on adoption of "a different PFS Relativity Adjuster, such as 40 percent, that represents a relative middle ground between the CY 2017 PFS Relativity Adjuster" and the current analysis.

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The ACC opposes the 25 percent PFS Relativity Adjuster and urges CMS to maintain the 50 percent PFS Relativity Adjuster through CY 2018 until it can complete the more detailed and precise analysis which it suggests will be forthcoming after CY 2017 claims data is available. A 25 percent PFS Relativity Adjuster creates many instances throughout the fee schedule where the OPPS PBD payment would be *lower* than the PFS payment. The College recognizes that the OPPS operates different from the PFS and that the aggregate payments to a PBD under the OPPS may not result in the steep cuts that are calculated on a case-by-case basis. However, CMS acknowledges that there is still insufficient data to validate this. Were CMS to finalize a 25 percent PFS Relativity Adjuster, the PFS payment rate should be a floor that overrides the 25-percent calculation.

A PFS Relativity Adjuster of 40 percent would also undervalue PBD services under the CY 2017 analysis that concluded the weighted differential between PFS and OPPS to be 45 percent. Since this analysis represents a broader spectrum of services than patient visits alone can provide, a 45 percent PFS Relativity Adjuster of 45% may be the most appropriate middle ground if CMS chooses not to maintain the 50 percent PFS Relativity Adjuster. While the ACC recognizes the intent of this PBD policy, CMS must ensure that any changes do not result in an unstable environment that threatens patient access to services.

Physician Quality Reporting System (PQRS) 2018 Payment Adjustment and the Value-Based Payment Modifier (VM) & Physician Feedback Program

The ACC supports efforts to align the final payment adjustments and reporting requirements for PQRS with the Merit-Based Incentive Payment System (MIPS) by lowering the 2016 performance year quality measure requirement from nine measures including one outcome measure to six measures with no outcome measure requirement. Likewise, the ACC supports the proposal to reduce the maximum amount at risk for the VM to +/- 2 percent for 2018. Performance data for 2016 has already been submitted; therefore, the College expects these changes to impact only a small number of clinicians and practices. However, the ACC appreciates all efforts by CMS to align the PQRS and VM with MIPS to provide a smoother transition for clinicians and practices.

Value-Based Payment Modifier (VM) & Physician Feedback Program

The ACC supports the proposal not to report VM data based on 2016 performance on Physician Compare in 2018. The College appreciates the Agency's recognition that posting VM data only for the final year of the program would be confusing for beneficiaries and also may not reflect true performance due to the changes proposed to the PQRS and VM requirements in this proposed rule. Releasing VM data in the form of a Public Use File (PUF) can provide researchers with data to help understand cost and resource utilization performance under the VM. Although individual practices have received VM performance data in the form of Quality Resource and Use Reports (QRURs) and Supplemental Quality Resource and Use Reports (sQRURs), overall performance trends have been difficult to quantify. The College agrees that while VM data on Physician Compare would not be of value to beneficiaries, the aggregate file data could help researchers and may provide insight into potential quality and cost performance trends that may occur under MIPS.

MACRA Patient Relationship Codes

The ACC supports the proposal for voluntary reporting of the proposed HCPCS/CPT modifiers on claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018. These codes will be used to attribute health care costs to individual physicians. As such, it is imperative they be accurate and standardized without undue administrative burden. At least calendar year 2018 should be used as a pilot period before any data are broadcast. Clinicians should have reasonable opportunity to review for accuracy and to avoid unintended consequences before any disclosures. The ACC also supports the proposed list of HCPCS modifiers in Table 26, but has learned that the AMA CPT Editorial Panel has approved CPT modifiers since this rule was written. The AMA modifiers, as written in the June CPT Editorial Panel minutes, should be used in lieu of those in Table 26.

The ACC emphasizes the importance of meaningfully piloting patient relationship modifiers while thoroughly educating clinicians and their practice staff. Through this testing, CMS should determine whether clinicians and practice staff understand how to properly utilize these codes and categories, and whether their use poses interruptions to the clinical workflow. CMS should also determine whether EHR vendors can implement these codes and categories and develop necessary software upgrades within the given timeline. CMS should take the feedback collected during this pilot period to make any necessary adjustments to the categories and codes themselves to ensure their accuracy, minimize administrative burden, and avoid unintended consequences.

Closing

Thank you for your consideration of these comments on the CY 2018 PFS proposed rule. Please contact James Vavricek, Associate Director, Medicare Payment & Coverage Policy, at 202-375-6421 or jvavricek@acc.org if you require any additional information.

Sincerely,

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