AMERICAN COLLEGE of CARDIOLOGY

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 1, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Room 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-1654-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Acting Administrator Slavitt:

The American College of Cardiology (ACC) is pleased to offer comments on the CY 2017 physician fee schedule proposed rule as published in the Federal Register on July 15, 2016. The College hopes its comments on this rule can inform the decisions made by the Centers for Medicare & Medicaid Services (CMS) to further our shared goals of improved healthcare for all Medicare beneficiaries. Items of particular interest to cardiovascular team members and their patients include:

1. Identification of priority clinical areas and the implementation of clinical decision support for use under the appropriate use criteria (AUC) program,
2. Collection of data on resources used in furnishing global services,
3. Unbundling inherent moderate sedation services, and
4. Reports of payments or transfers of value to covered recipients (Open Payments).

ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College 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, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. The ACC also produces the *Journal of the American College of Cardiology*, ranked number one among cardiovascular journals worldwide for its scientific impact.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Priority Clinical Areas

In CY 2016 rulemaking, CMS finalized a plan to identify outlier ordering professionals from within priority clinical areas that would be established through subsequent rulemaking. The College supported the identification of outliers based on priority clinical areas that consider volume, variability of appropriate utilization, strength of evidence, and clinical area of care. The purpose of the AUC program should be to identify meaningful outliers. If CMS selects a priority clinical area and the variability among providers is narrow, CMS should not waste resources by imposing prior authorization on these providers. It should instead focus on identifying outliers in clinical areas where there is wide variance in appropriate ordering patterns.

The College believes that the current methodology of identifying priority clinical areas based on ICD-9 diagnosis codes and Medicare payments is flawed and that CMS should explore a different methodology, particularly if the Agency plans initial implementation of AUC consultation for priority clinical areas only. Appropriate use criteria (AUC) are based on clinical scenarios, ICD-9 codes are not. At the point of care, a clinician may not know which set of criteria would fit a scenario such as painful respiration (786.52), which may trigger the need to order an echocardiogram, CT, pulmonary angiogram, or other test. Similarly, several sets of criteria may contain indications for a "not otherwise specified" chest pain diagnosis (786.50). The indication is often documented after the test is completed and interpreted. If CMS takes a focused approach and implements AUC consultation based on a few priority clinical areas by diagnosis, a physician may not know whether he or she is required to consult with AUC though a qualified clinical decision support mechanism (CDSM) at the time he or she is ordering the test because the diagnosis is not yet known. Defining priority clinical areas by diagnosis would create confusion rather than flexibility to ordering physicians.

The ACC recommends that CMS explore alternative methodologies between now and the CY 2018 rulemaking process for better identifying priority clinical areas. One approach would be to identify priority clinical areas based on service (CPT Code) and anatomical region. This system would be better at guiding physicians which tests fall under a priority clinical area and thus require consultation with AUC through a qualified CDSM during the clinical decision-making process. Classifying these areas by diagnosis would help with any post-hoc analysis, but would not serve any benefit as decision support at the point of care.

Identifying priority clinical areas solely based on diagnosis code and utilization does not identify whether or not improvements in appropriate utilization can be achieved through the AUC program. For example, the dataset shows that Chest Pain accounts for 12% of total services and 14% of total payments under Medicare Part B in 2014. However, what this data does not tell is what percentage of services are appropriate, sometimes appropriate, or rarely appropriate. In identifying outliers across priority clinical areas, CMS should focus on those areas where there is significant variation in ordering patterns and improvements in utilization appropriateness can be made. **Before finalizing the priority clinical areas, CMS should collect at least one year of data from the start of the program and use it to identify areas where the program can help reduce variation.** The AUC program should target those ordering physicians who are true

outliers and not penalize those who happen to be at the edge of a group that does not have significant variance in ordering patterns.

The ACC appreciates CMS's transparency in providing the data behind its initial priority clinical area analysis on the CMS website. The College encourages CMS to continue sharing this information with stakeholders as the Agency refines the methodology.

Mechanisms for AUC Consultation

The ACC commends CMS on the proposal to establish requirements for qualified clinical data support mechanisms (CDSMs) while still retaining the flexibility that will allow for the development of different mechanisms early in the program. This flexibility will allow the marketplace to develop solutions that are best suited for a wide variety of providers' needs.

CDSM Qualifications and Requirements

Data Standards

CMS proposes that, at least initially, it is in the best interests of the program to establish CDSM requirements that do not prescribe specific IT standards. Instead, it proposes to focus on the functionality of and capabilities of qualified CDSMs. The ACC supports this strategy in theory because it may allow for the development of CDSM that is integrated into provider workflow in the most effective way to facilitate patient care. However, the College cautions CMS to consider the implications of systems that originate unstructured patient data. Unstructured data cannot be integrated easily into the EHR, nor can it be exchanged easily between healthcare organizations. The College also urges CMS to consider both the financial and operational impact on providers if future guidance requires CDSM implementers to upgrade their systems from uncertified systems to ONC certified technology. **In the event that CMS does issue future guidance on the use of ONC-certified CDSMs, the College recommends that CMS hold clinicians harmless for a reasonable period of time, to be determined based on research indicating the length of time needed to select and implement a new system after such guidance is issued.**

Privacy and Security

The ACC supports CMS's proposal that the qualified mechanism must meet privacy and security standards under applicable provisions of law, such as the HIPAA Privacy and Security rules. However, a proliferation of CDSM mechanisms developed in the early stages of the program could result in the implementation of mechanisms that are especially vulnerable to exploitation for illegitimate purposes. These vulnerabilities could result in the disclosure of sensitive patient information including Protected Health Information and Personally Identifiable Information. It is critical for qualified CDSMs to be secure against the growing frequency, scope and sophistication of cyberattacks. **The College urges CMS to finalize requirements for qualified mechanisms to meet codified privacy and security standards, as well as incorporate recommendations from the National Institute of Standards and Technology (NIST) voluntary framework for reducing cyber risks to critical infrastructure, as soon as possible.**

Interoperability of Qualified CDSM Mechanisms and Certified EHRs

Ideally CMS's flexibility in allowing for the development and implementation of a variety of qualified CDSMs would result in a range of qualified CDSMs, some that are stand-alone systems that exchange minimal information with the EHR, and some fully integrated and interoperable with the EHR. Crucial to any degree of interoperability between qualified CDSMs and EHRs are the common standards that enable the exchange of clinical information. The advantages of sharing data between the CDSM module and the EHR include improved clinician workflow by eliminating duplicate data entry when consulting AUC, patient records that include the results of AUC for a particular procedure, and the ability to exchange patient records with other health care organizations that include the results of AUC. However, the College has some concerns regarding the coordination of the five-year application and approval cycles for qualified CDSMS, and certification of EHRs specified by the EHR Incentive Program. It is likely that EHRs certified by the ONC would need to undergo recertification due to changes in the common standards needed for interoperability. Will such systems also need to be requalified as CDSMs for the purposes of the AUC program? The ACC highlights the importance of addressing this question in rulemaking or guidance. **The College cautions CMS to consider the impact of changes to the EHR certification requirements on integrated qualified CDSMs that are still in the five-year application and approval cycles and recommends that CMS consider future alignment between the two programs to ensure system functionality and maintain clinician productivity.**

Future Considerations

While the ACC believes that flexibility in the early stages of developing and implementing CDSMs for AUC is crucial to foster development of the most useful systems, the College believes that for CDSMs to fulfill their potential in supporting patient care, additional functionality and interoperability with the EHR should be incorporated in future iterations. **ACC recommends that these functionalities should include:**

- Integration of claims data in the patient record
- Prior authorization status
- Bi-directional exchange of information between imaging ordering clinician and imaging furnishing provider through the EHR
- Imaging order status
- Results of imaging interpretation

Adding these functionalities to the requirements for qualified CDSMs will ensure that CDSM capabilities can be fully integrated into the EHR, improving clinical workflow and allowing for a greater focus on patient care. The recently published *2016 ACC/ASE/ASNC/HRS/SCAI Health Policy Statement on Integrating the Healthcare Enterprise* expands further on ACC's belief that meaningful interoperability of data is necessary to support a robust and transparent healthcare delivery system.

Approval Cycle for Qualified CDSMs

CMS proposes a five-year application and approval cycle for qualified CDSMs, intended to align with the five-year application and approval cycle for qualification of Provider Led Entities (PLE). **CMS also proposes that CDSMs that fail to meet the requirements set by CMS may lose qualification at any time. While the ACC supports this, the College recommends implementing a safeguard for practices that may be using one of these unqualified systems.** Physicians and practices should not be penalized because the vendor's product loses qualification. CMS should provide a 12-month period in which physicians can transition to a new CDSM. During this time, physicians should be permitted to use their existing CDSM under a grandfathered status.

Specialty-Specific CDSMs

The ACC recognizes CMS' statement that requiring that CDSMs offering a full library of AUC across all priority clinical areas will eliminate the possibility that an ordering professional will need to use more than one CDSM. While it is likely that primary care physicians and those in a multi-specialty practice or hospital will benefit from an all-inclusive CDSM, the ACC is concerned that such a system may be burdensome to single-specialty physicians. A cardiology practice ordering cardiology-specific advanced imaging services will typically only consult with cardiology appropriate use criteria. If this practice were required to purchase and implement an all-inclusive CDSM, this practice may end up paying to license multiple sets of criteria that it will never even use.

The ACC recommends that CMS permit the development of specialty-specific CDSMs. These CDSMs should be required to include several sets of criteria for a given specialty area so that physicians still have a choice of which set they would consult. The ACC recognizes that there may be infrequent instances where a specialist orders a test outside of his or her typical patient population. For example, a physician in a cardiology practice may order a test for low back pain during a non-routine patient encounter or clinic encounter. For these cases, CMS should encourage physicians to utilize the free CDSM option rather than logging a non-applicable result.

CMS should also consider whether or not to implement a threshold for AUC consultation that would exempt these one-off cases or low-volume providers (e.g., AUC consultation is required for services that a physician orders more than ten times, based on CPT code). While there is value to requiring that all physicians consult with AUC for all advanced imaging services, the College understands that there should be a balance to ensure that the program is not burdensome. Implementing such a threshold would ensure that physicians can focus on changes to their practice patterns for the primary services that they order.

Exceptions to Consulting and Reporting Requirements

The ACC supports exceptions to reporting for imaging services ordered for an individual with an emergency medical condition, including any encounters that may occur outside of the emergency department. The College also supports the proposal to apply to the exception

also to cases where the physician initially determines that the patient has an emergency medical condition prior to ordering an advanced imaging service, but is later determined not to have had an emergency medical condition. These policies will ensure that patient health is not jeopardized by any delays caused by the physician determining whether or not AUC consultation is necessary during a potential emergency scenario.

The College recommends that CMS closely monitor the above exception to ensure that it is properly implemented. Chest pain is indicated as a priority clinical area for program implementation; however, many patients present with emergent chest pain symptoms. It may be the case that many tests ordered by a physician fall under this exception. CMS should work closely with physicians and practices to ensure that they understand how to properly document and code this exception. Physicians should not be penalized or targeted for having high-exception rates if that is reflective of their patient population.

The ACC also supports the exception for inpatient services paid under Medicare Part A. CMS should ensure that this exception is clearly implemented in alignment with the hospital short stay policy. If an admitting physician expects the patient to require a stay of at least two midnights, supported by medical documentation, and the actual stay is less than that threshold, then that physician should not have been required to consult with AUC for that patient.

Finally, the College supports the third exception for eligible professionals excepted from the EHR Incentive Program, as this would easily capture physicians who may have a significant hardship in implementing a CDSM.

Potentially Misvalued Services

Collecting Data on Resources Used in Furnishing Global Services

In response to the Medicare Access & CHIP Reauthorization Act (MACRA) provision prohibiting implementation of CMS's previous proposal to eliminate 10- and 90-day global period payment systems and requiring CMS to gather necessary information to correctly value these services, CMS proposes a "three-pronged approach to collect timely and accurate data on the frequency of, and inputs involved in furnishing, global services including the procedure and the pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment."

1. Comprehensive claims-based reporting about the number and level of pre- and postoperative visits furnished for 010- and 090-day global services.
2. A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
3. A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.

The comprehensive claims-based reporting program devised by CMS in this proposed rule would have physicians report a series of eight G codes in 10-minute increments that identify place of service and complexity of the time.

Inpatient	GXX X1	Inpatient visit, typical, per 10 minutes, included in surgical package
	GXX X2	Inpatient visit, complex, per 10 minutes, included in surgical package
	GXX X3	Inpatient visit, critical illness, per 10 minutes, included in surgical package
Office or Other Outpatient	GXX X4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package
	GXX X5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package
	GXX X6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package
Via Phone or Internet	GXX X7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package
	GXX X8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package

Moving forward as proposed would create an immense burden on physicians and their staff. New systems and staff would have to be deployed to ensure accuracy. Every instance in which a 10-minute increment went unreported due to an error anywhere in the system would underreport the time and complexity of the post-operative work. **The ACC strongly urges CMS not to finalize this proposal and instead focus on data collection from a representative sample of physicians and high-volume services.** CMS should dispense with this large-scale data collection and direct Rand to work closely with specialties on the broad survey described as the second prong of its program. Doing so would increase the likelihood of a successful survey. This would be consistent with the Congressional language in MACRA. Should CMS still choose to pursue a claims-based data collection, this could be done by having physicians report code 99024, *Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure,* to identify the number of post-operative visits.

Services with Moderate Sedation as an Inherent Part of the Procedure

CMS and stakeholders noticed several years ago that certain services which included the work and resources of moderate sedation as an inherent part of the procedure were increasingly being reported with separately reported anesthesia services. This means that CMS was paying twice for patients to be sedated/anesthetized. In response, the CPT Editorial Panel created CPT codes to separately report moderate sedation services in association with the elimination of Appendix G from the CPT manual for CY 2017. The RUC recommended values for those codes and also recommended a methodology to systematically revalue all services in Appendix G.

CMS proposes to remove 0.25 work RVUs that correspond to new code 991X2, *Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older*, from all non-gastroenterology services. When moderate sedation is provided by the same physician performing the service, that physician would report 991X2 in addition to the code for the underlying service. The net work RVU for the two codes would equal the previous work RVU for the underlying code when it included inherent moderate sedation. New code 991X5, *Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time*, would be reported to capture the resources for maintaining moderate sedation. When moderate sedation is provided by a second who is not performing the service, it would be separated reported and paid using parallel codes.

The ACC understands the appeal of this one-step value adjustment methodology. However, certain concerns that ACC has expressed at CPT and the RUC and in previous comments to CMS remain unaddressed by this proposal. The first is that utilization data clearly show moderate sedation is still inherent in many procedures. **The ACC repeats its recommendation that moderate sedation only be unbundled and reported separately for services where it is clearly no longer typically provided by the same physician while leaving it intact for services for which it obviously remains inherent.** While the typical threshold of "more than 50% of the time" may not be high enough for inherent moderate sedation, services inclusive of inherent moderate sedation that are billed without separate anesthesia 90% of the time could be removed from this revaluing project. A second concern is the removal of 0.25 from all non-gastroenterology services. For lower-valued services this reduction constitutes a significant portion of the overall work RVU. **The ACC recommends CMS make smaller reductions to codes with values below 1.00 work RVUs. At a minimum, CMS should follow its rules for phase-in of significant RVU reductions greater than 20%.**

Finally, this change undoubtedly creates new administrative burdens for physicians. In addition to billing a separate code when performing moderate sedation that was previously inherently bundled into a service, physicians will also have to closely monitor and document sedation times in a manner that billing staff can use to bill for the additional 15-minute increments. CMS should

work closely with societies to ensure physicians and billing staff have ample time to adapt to this new system. It will also be important for CMS to emphasize that code 991X5 for additional 15-minute increments should also be billed in the facility setting even though no physician work is associated with it. The absence of physician work in that code may create an incentive for it to be ignored, but it will be relevant to hospital cost reporting and impact future payments in the hospital inpatient and outpatient prospective payment systems.

Improving Payment Accuracy for Care Coordination Services

Complex Chronic Care Management Services

Changes in care delivery in have motivated CMS to rethink the way it pays for care coordination service in recent years. While not perfect, the ACC has supported expansions into payment of non-face-to-face services through transitional care management and chronic care management codes. **The ACC supports CMS's proposal to recognize codes 99487 and 99489 for complex chronic care management.**

Non-Face-to-Face Prolonged E/M

The ACC has previously expressed support for payment of services defined by existing CPT codes for which CMS declined separate payment in the past as a way to encourage care coordination**. The College supports CMS's proposal to cover prolonged E/M services 99358 and 99359**. However, CMS departed from CPT in an important aspect of the services. CMS proposes to require the services be furnished on the same day by the same physician as the companion E/M code. The CPT manual requires no such linkage, and in fact states, "This prolonged service may be reported on a different date than the primary service to which it is related." **CMS should implement the services in this fashion and not require them to be provided on the same day as the companion E/M**.

Valuation of Specific Codes

Left Atrial Appendage Closure (333X3)

CMS proposes a work value of 13.00 relative value units (RVUs) for the new Category I CPT code 333X3 that describes the work of closing the left atrial appendage with an implant *(Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation)*. This value corresponds with the survey minimum response, and is less than the RUC recommendation of 14.00 RVUs. **The ACC opposes CMS's proposed work RVU of 13.00 for 333X3 and recommends CMS adopt the value of 14.00 originally recommended by the RUC.**

CMS incorrectly indicates that the RUC's 14.00 RVU recommendation is the survey 25th-percentile value. In fact, the survey 25th-percentile value is 19.88 work RVUs. CMS also indicates that it considered 333X3 in comparison to "key reference codes discussed in the RUC

recommendations with higher intraservice and total service times" as part of its rationale to reduce the work RVU. The RUC recommendations submitted to CMS referenced codes 93583 (*Percutaneous transcatheter septal reduction therapy (e.g., alcohol septal ablation) including temporary pacemaker insertion when performed*) and 37244 (*Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation*). Those services have times of 90 minutes intraservice, 188 minutes total time and 90 minutes intraservice, 176 minutes total time, respectively. The service time recommendations that CMS proposes to adopt from the RUC are 90 minutes intraservice, 183 minutes total time, squarely between 93583 and 37244. 93583 and 37244 both have work RVUs of 14.00. The identical intraservice times and similar total service times, as well as the clinical similarity of two services that both involve catheter-based, cardiovascular therapies, support the RUC's crosswalk recommendation of 14.00 work RVUs. It is unclear to what services CMS compared 333X3, but it appears it was not the same 93583 or 37244 cited by the RUC in its recommendations.

More generally, the ACC continues to be alarmed by the arbitrary and opaque decision-making process CMS sometimes uses when it sets work values that differ from the multispecialty, expert RUC process. Three entire sentences were used to inaccurately summarize the RUC survey results, inaccurately characterize the RUC recommendation, and to determine that in the Agency's "clinical judgement" a lower value is more accurate. This perfunctory and errant treatment suggests that CMS did not understand the information it was given. Further, it is difficult to understand what clinical judgement the Agency can have about the work required to perform a breakthrough, transcatheter therapy provided at dozens of sites by a few hundred physicians since it was approved by the FDA in March 2015. The ACC again implores CMS to more completely explain its thought process when making these decisions by citing reference codes and explaining the specifics of its clinical judgement in the future.

Closure of Paravalvular Leak (935X1, 935X2, and 935X3)

CMS proposes to assign work RVUs less than the RUC recommendations for each code in this family. For 935X1 (*Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve)* and 935X2 (*Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve),* CMS used the same building-block methodology as the RUC, but started with a lower-valued initial crosswalk that it believes is more accurately reflects the time and intensity of the services.

The RUC recommended the work value of 17.97 for 935X2 be crosswalked from code 93580 *(Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant).* These codes have nearly identical service times and are both percutaneous transcatheter procedures to treat structural heart disease. Instead, CMS proposes to crosswalk the work RVU of 14.50 for 935X2 from code 37227 *(Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed).* These two codes also have similar service times and are both percutaneous. However, CMS's proposal fails to correctly recognize the higher intensity of 935X2 in

relationship to 37227. 935X2 is a service that treats a structural defect inside the heart, not an obstructed artery in the leg. The clinical similarities and higher intensity of transcatheter structural heart therapies matter. **The ACC disagrees with this proposal that incorrectly links a percutaneous transcatheter structural heart therapy to a lower extremity revascularization therapy that is less intense and recommends CMS adopt the RUC recommendations for these services.** The below table demonstrates the anomaly CMS would create were it to value temporally and clinically similar services in a fashion that ignores the higher intensity of percutaneous transcatheter structural heart therapies.

Code	Short Descriptor	Work RVU	Intraservice Time	Total Time	IWPUT
93580	Transcatheter closure of atrial septal defect	17.97	120	210	0.1329
935X2	Transcatheter closure of aortic paravalvular leak	TBD	120	208	TBD
37227	Femoral, popliteal stent and atherectomy	14.50	125	203	0.1026

After CMS corrects this error, it can then also correctly value 935X1. Recognizing that the work of 935X1 consists of 935X2 with the addition of a transseptal puncture to access the mitral valve, the RUC recommended a building block methodology that adds the work RVU of 3.73 from add-on code 93462 (*Left heart catheterization by transseptal puncture through intact septum or by transapical puncture)* to the recommendation of 17.97 for 935X2. This produces a work RVU of 21.70 for 935X2. CMS proposes to add the work RVU of 3.73 to its value of 14.50 for 935X2. This produces a work RVU of 18.23 for 935X2. **The ACC supports CMS's decision to apply this same building block methodology, but reiterates that the work RVU for 935X2 should be the higher 17.97 value and the resulting work RVU for 935X1 should be 21.70.**

The final code in this family is an add-on for placement of additional prostheses. It can be used for either the mitral or aortic valve services. The RUC recommended the survey 25th-percentile work RVU of 8.00 for code 935X3 *(Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary service)* with the survey median intraservice time of 60 minutes. To support this recommendation, the RUC compared 935X3 to code 33884 *(Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure).* This service has an identical 60 minutes intraservice time. It also has several clinical similarities to 935X3—it is an endovascular repair and involves placement of a prosthesis. CMS proposes a lower work RVU of 6.81 for 9358X3, crosswalked from a different 60-minute add-on code, 35572 *(Harvest of femoropopliteal vein, 1 segment, for vascular reconstruction procedure (eg, aortic, vena caval, coronary, peripheral artery) (List separately in addition to code for primary procedure).* This service is only similar to 935X3 in that it is cardiovascular in nature. Surgical harvest of a lower extremity vein is not clinically similar to the transcatheter percutaneous structural heart therapies already discussed. 9358X3 is an additional unit of 9358X1 or 9358X2 and should have a similar, higher intensity—as shown in the below table—that aligns with the RUC recommendations for 9358X1 and

9358X2. **The ACC recommends CMS adopt the RUC recommendation of 8.00 for code 935X3.**

Code	Short Descriptor	Work RVU	Intraservice Time	Total Time	IWPUT
33884	Placement of endovascular prosthesis extension, additional extension	8.20	60	60	0.1367
935X3	Transcatheter closure of paravalvular leak, additional prosthesis	TBD	60	60	TBD
35572	Femoropopliteal vein segment harvest	6.81	60	60	0.1135

Determination of Practice Expense RVUs

Practice Expense Inputs for Digital Services

In addition to the Picture Archiving and Communication System (PACS) workstation used by clinical staff acquiring images and furnishing the technical component of digital imaging services, CMS proposes to create a direct practice expense equipment input for a "professional PACS workstation" that is used by the practitioner interpreting the image in the furnishing of the PC of many services. The ACC appreciates CMS's acknowledgement of this workstation and supports its use in codes 75557-75574 that are performed by some cardiologists. However, CMS proposes to allot equipment time equal to half the physician work preservice time and the intraservice time**. The College urges CMS to increase the allotted equipment time to align with the *entire* physician work preservice and intraservice times.** This methodology would be consistent with recommendations made by the AMA RUC following recent meetings.

Reports of payments or other transfers of value to covered recipients

Much has been made by the media of the relationships that exist between physicians and industry. The cardiovascular community certainly understands these concerns and has taken numerous steps to enhance the relationship between patients and physicians, including incorporating protections against industry influence on patient care. Ensuring that patient interests remain central to medical care is one of the central tenets of the ACC's Code of Ethics. Because of this ethical imperative, the College has committed itself to transparency in its relationships with industry. According to the Code of Ethics, "[p]atient welfare must be paramount in the practice of medicine. Under no circumstances shall a member place his or her self-interest above patient welfare." In keeping with that, the ACC adopted and made public its *Principles for Relationships with Industry*. These principles govern all of the interactions between the College and its leaders and industry. For instance, the College limits the number and types of relationships physicians may have with industry before joining a writing committee for a clinical document. The ACC also requires certain relationships between individual physician volunteers or paid participants and industry be made public in order for those individuals to participate in specified activities. All leaders of the ACC must submit information pertaining to their relationships with industry and absent themselves during discussions pertaining to the particular relationship.

That said, while the ACC is sensitive to the public's concerns and the appearance of impropriety of these relationships, it is crucial that CMS and the American public understand that there is nothing nefarious about the large majority of them. **ACC believes relationships with members of industry provide value when such relationships are ethically structured.** To this end, the College publishes information about its relationships and its policies that ensure such relationships have no influence on educational or scientific content or on decisions pertaining to patient care. Particularly today, with the paucity of public funding available for continuing education, quality initiatives, and research, industry support is essential to provide the high level of education and cutting-edge science that has so dramatically advanced the quality of patient care and improved outcomes in cardiovascular care in the last decade.

Educational materials

In this vein, the ACC continues to support the objectives of the Sec. 6002 of the Affordable Care Act (ACA). However, the College continues to have concerns regarding the interpretation and implementation by CMS of this provision of the ACA. Congress specifically included in the Physician Payment Sunshine Act 12 categories of items excluded from the reporting requirements. The ACC believe that CMS has misinterpreted Congress' intent behind the exclusion for "[e]ducational materials that directly benefit patients or are intended for patient use." CMS fails to recognize the direct translation of materials from independent peer-reviewed medical journals, certified CMS and medical textbooks into improved patient care. If the development of a strong scientific foundation and enhancement of clinician knowledge is not a direct benefit, then what is? **To that end, the ACC allies itself with comments submitted by the American Medical Association on this subject.**

Physician review of data

Given the potential harm to a covered recipient's reputation and the physician-patient relationship, physicians must have the opportunity to review these reports before they become public. Even two years after the implementation of the Open Payments program, few physicians have reviewed the information reported about them prior to the publication. This is primarily because of two reasons: a lack of actual notice and the complexity of the registration process.

<u>Actual notice</u>

CMS continues to assume that providing actual notice to covered recipients of the report review period will be burdensome and difficult to accomplish. Instead, the Agency believes that sharing this information through its website and listserv announcement constitutes the equivalent of notice. These methods are simply not adequate. At some point, CMS must acknowledge that most clinicians do not regularly visit its website, nor do they receive its listserv announcements directly. Thus, using only its own electronic communication mechanisms is inadequate and does not meet the statutorily-imposed obligation to provide actual notice to affected individuals and organizations.

Instead, the ACC urges CMS to provide actual notice to physicians using systems that already exist. Both CMS and applicable manufacturers have access to the information of covered

recipients through the National Plan and Provider Enumeration System (NPPES) Database, the same database that the Agency recommends applicable manufacturers use to obtain the National Provider Identifiers (NPIs) of covered recipients and that the Agency uses to verify physicians' Medicare enrollment information. This same system can be used to obtain contact information to provide actual notice. The Agency provides clinicians with actual notice of a wide variety of information on a regular basis through claims remittances, electronic communications and letters sent via the US Postal Service. **In addition to publicizing the pre-publication period through its listservs and website, the ACC urges CMS to avail itself of the same channels it uses to communicate with clinicians regarding provider re-enrollment, claims status and other matters that must be communicated directly to clinicians or their employers.** Additionally, applicable manufacturers should have contact information for those covered recipients to whom they provide direct funding and those who they designate to receive funding on their behalf. **The ACC continues to support the provision of actual notice of the report review period to covered recipients, as well as to third parties referenced in the reports because of indirect payments or transfers of value to covered recipients, and believes that it is not the overwhelming or complex task described by CMS.**

Pre-publication information verification

Rather than acknowledging barriers imposed upon clinician access to their own data by CMS' security protocols, the Agency has complicated the situation even further by requiring clinicians to register multiple times to gain access to a wide variety of reports. Clinicians must pass through at least two different registration processes to obtain access to their Open Payments reports prior to their publication. Additionally, the first system requires re-registration every 60 days. Given how infrequently clinicians need to access this system (at most two to three times per year), this adds yet another layer of complexity, taking time away from patient care should clinicians determine this is important. **Instead of creating barriers for clinicians to waste time addressing, the ACC urges CMS to create a system that encourages clinicians to review the data the Agency collects on them, particularly prior to publication.** It does not benefit anyone for CMS to publish incorrect data and could in fact cause significant harm to the clinician-patient relationship if erroneous data is published.

To that end, the ACC supports the concept of requiring applicable manufacturers to share Open Payments data with physicians before it is reported to CMS. A pre-vetting process would potentially enable physicians to bypass CMS' overly complex and burdensome system while still ensuring that the data reported to the Agency is accurate. That said, the College does have some concerns about the potential for multiple portals requiring multiple passwords to be the process by which this pre-vetting process is conducted. **The ACC urges CMS to work with vendors of existing platforms that collect such or similar data to determine a process for pre-vetting that will enable physicians to verify their data without reducing the time they have available for patient care.**

Report Corrections

CMS would only allow for reports to be corrected on an annual basis, and corrections are limited to a narrow time period. Any additional corrections have to wait a full year to be made public or

are not be made at all if they were from previous years. Incorrect reports could potentially cause significant harm to a covered recipient's reputation. **Thus, the ACC urges CMS to accept reports and updates to the reports throughout the year on the current reporting year and all preceding years.**

Given the statutory requirements and potentially significant penalties, it will be to the benefit of applicable manufacturers to report as much information as possible. The College does not believe these entities will intentionally report inaccurate information; however, erroneous information will inevitably be reported to the government in large part due to the large volume of information that will be transmitted. **Thus, the College urges the Agency to correct reports in real-time.**

Recoupment of Payments to Providers Sharing the Same Taxpayer Identification Number

Under Sec. 6401(a)(5) of the Affordable Care Act, the Secretary is given the authority to recoup or offset overpayments to one provider or supplier from another under the same Taxpayer Identification Number (TIN). CMS proposes that, as part of its implementation, it would not require Medicare contractors to notify all affected parties in advance of a recoupment or an offset, only the obliged party. However, CMS fails to provide any explanation as to why it should not be required to provide notice to the applicable party, as well, other than this is a common practice by the Department of Treasury. The Agency assumes that it does not cause difficulties for providers or suppliers, simply because the Department of Treasury has elected not to provide healthcare businesses with this critical information.

There is no requirement that all parties under a TIN share a billing office, so the billing office of one party may have no knowledge of the activities of the other. The lack of notice to all affected parties could create significant confusion, generating additional work for both the providers or suppliers of services, but the Medicare contractors, as well, as they are forced to deal with additional questions from the affected providers or suppliers who attempt to understand unexplained reductions in payments or recoupments of funds. **To that end, the ACC urges CMS to require its contractors to provide notice to applicable providers of their intention to recoup or offset payments in the event that the funds are unable to be collected from the applicable provider or supplier of services.**

The College does not believe that the notice furnished through articles, updates to the Internet Only Manual or clarifying language in demand letters issued to obligated providers is sufficient. Instead, the Medicare contractors should be required to provide notices to applicable providers or suppliers that are tailored to the individual situation and specify that the recoupment or offset is occurring because of an overpayment to the obligated provider or supplier. The ACC would welcome the opportunity to work with CMS to develop language for such notices.

Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

The ACC supports the proposal to permit Eligible Professionals (EPs) that bill under the TIN of an ACO participant to report separately for purposes of the 2018 PQRS payment

adjustment and secondarily, the 2017 payment adjustment, when the ACO fails to report on behalf of EPs who bill under that TIN. This policy is aligned with the College's position that EPs should not be penalized based on inaccurate data outside of their control, or in this instance, the lack of data due to circumstances outside their control.

The ACC also supports the related proposals that would allow affected EPs to submit via a registry, Qualified Clinical Data Registry (QCDR), direct EHR or EHR data submission vendor; however, CMS should be aware that many clinicians in an ACO will not be reporting data to these vendors during the performance year if they are operating under the assumption that their ACO entity is reporting on their behalf. The ACC encourages CMS to communicate early and directly with affected clinicians so they clearly understand their situation and can take action to submit data and avoid PQRS and Value-Based Modifier penalties. CMS must allow ample time for those clinicians and groups that decide to submit their own PQRS data to work with an EHR, qualified registry, or QCDR vendor to pull the necessary data for CMS. It takes time for vendors to enter into data use agreements with clinicians, map to the EHR, pull, and validate information for submission. The College is concerned that if a clinician does not find out until the end of the performance period that the ACO entity failed to report on his or her behalf, this proposed solution may not actually be available if vendors are unable to pull and submit data within CMS' timeline.

Traditionally, CMS has not accepted PQRS data from clinicians or groups who are part of an ACO. While there are operational concerns as noted above, the College believes that this proposed policy is a step forward in the right direction. As CMS transitions to the new Quality Payment Program under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the ACC recommends that CMS maintain this proposed policy. Furthermore, the ACC encourages CMS to use this as a starting point for determining the feasibility of collecting quality performance data from ACO participants at both the entity and individual clinician levels. The ability to collect both levels of data would allow clinicians who are performing high-quality care at an individual level to still be rewarded under the Merit-Based Incentive Payment System (MIPS) even if it is not reflected through the metrics reported at the ACO level.

Medicare Shared Savings Program

Changes in the Quality Measure Set

The ACC supports efforts to align the Shared Savings Program quality measure set with those measures recommended by the Core Quality Measures Collaborative (CQMC). The alignment of measures across Medicare, private, and government payer programs will allow clinicians to better focus on effective clinical care rather than the differences in measure specifications across payers.

Proposed Expansion of the Diabetes Prevention Program (DPP) Model

The ACC supports expanded access to diabetes prevention programs as type 2 diabetes is a known risk factor for the development of cardiovascular disease. Providing Medicare beneficiaries with support to manage their blood glucose levels and adopt healthier lifestyle

behaviors can lead to savings in the treatment of diabetes and associated chronic conditions. However, as with any Medicare program, the ACC encourages CMS to carefully monitor for unintended consequences as the Medicare DPP is expanded. CMS must ensure that the DPP achieves the goals of reducing Medicare spending without reducing the quality of care provided to beneficiaries or limiting their access to other services.

Learning Activities

CMS intends to coordinate with the Centers for Disease Control (CDC) to provide technical assistance to DPP organizations. In addition to information from the CDC, CMS should encourage partnerships between DPP organizations and medical specialty societies such as the ACC. The ACC's CardioSmart education and empowerment initiative includes resources on prediabetes, diabetes, and cardiovascular disease targeted at patients and their caregivers. DPP organizations should be encouraged to share this information and to educate beneficiaries on the relationship of the DPP coach to the rest of the beneficiary's clinical care team. While the DPP coach provides valuable services that can improve the beneficiary's health, it should be clear that coaching is not a replacement for clinical care.

Quality Monitoring and Reporting

As with any Medicare program, quality monitoring and reporting is crucial to ensure that initiatives contribute to improved beneficiary outcomes. CMS can implement a program similar to that currently being utilized under the Home Health Quality Reporting program which utilizes a combination of process and outcome measures.

The Medicare DPP provides the opportunity to introduce patient-reported outcome measures such as daily weight, activity, and blood pressure. The ACC recognizes that these measures would take work to develop, and that factors such as beneficiary adherence must be taken into account; however, they may provide valuable data on the impact of the Medicare DPP on beneficiaries.

Timing of the MDPP Expansion

The ACC supports a phased-in approach to expanding the Medicare DPP. While exercise and lifestyle modification is the preferred primary approach to managing weight gain and preventing the onset of diabetes, there are many beneficiaries for whom lifestyle modification may not be enough, either due to an inability to maintain long-term adherence or other risk factors. The Office of the Actuary evaluated results of the Medicare DPP demonstration based on two years of data. CMS should begin expansion of the program in areas with high rates of obesity and diabetes. The initial expansion should include a diverse set of metropolitan statistical areas (MSAs) representing rural, urban, and Health Professional Shortage Areas so that CMS can assess the long-term success of the program across different regional areas. As more experience is gained with the program, and as CMS can ensure the quality of each MDPP provider in a region, gradual expansion can continue. Full national implementation should not occur until it is supported by longer-term financial and beneficiary outcome data.

Fraud and Abuse

The DPP introduces new Medicare provider types into the beneficiary's care team. Beneficiaries participating under a Medicare DPP may work with non-clinical lifestyle and behavioral coaches in non-clinical setting. The ACC supports the requirement that MDPP organizations be subject to the enrollment requirements and screening similar to what is in place for home health agencies to minimize the potential for Medicare fraud and abuse.

The ACC appreciates the opportunity to offer comments on the many proposals contained in this rule. If you have any questions or wish to discuss these comments further, please contact James Vavricek, Associate Director of Regulatory Affairs, at 202-375-6421 or jvavricek@acc.org.

Sincerely,

Richard A. Chazal, MD, FACC
President