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September 11, 2019

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

RE: CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2020, published in the August 14, 2019 Federal Register (Vol. 84, No. 157 FR, pages 40482-41289). The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

The proposed rule includes both policy updates and many modifications to individual inputs for physician fee schedule services within the Resource-Based Relative Value Scale (RBRVS) upon which the ACC provides feedback. In this letter the ACC will focus on payment policy and technical changes that drive payment for individual services in hopes of giving CMS staff adequate time to incorporate revisions into the fee schedule after the proposed rule was published much later than normal. A later letter will address other programmatic issues.

In addition to other topics, this letter includes significant comments on:

- Valuation of work and practice expense (PE) inputs for specific services with significant attention paid to the technical component pricing of positron emission tomography myocardial perfusion imaging;
- Payment for evaluation & management (E/M) services;
- Updates to professional liability insurance (PLI) inputs.

Valuation of Specific Services

Codes for many cardiovascular and related services were reviewed by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) during the CY 2020 cycle. Detailed comments on changes CMS proposed to the RUC recommendations for many of these services follow below. The RUC coordinates with specialty societies in developing comments, so many pieces of feedback on specific code values will look familiar and echo the comment letter already submitted by the RUC that focuses on the correctness of the original RUC recommendations. The Agency also proposed to implement several sets of recommendations without modification. **The ACC supports work and PE proposals related to self-measured blood pressure monitoring, ambulatory blood pressure monitoring, transcatheter aortic valve replacement (TAVR), and septostomy and urges they be implemented in the final rule.**

In discussion of the TAVR codes the proposed rule references concerns that reductions in time from when the technology was initially introduced not "match" reductions in surveyed work time, and that further scrutiny will be necessary in light of the related proposed national coverage determination posted in March 2019. Regarding the latter point, the final national coverage determination posted in June modified some criteria regarding facility and operator experience but did not fundamentally change the approach to covering this important therapy for patients with symptomatic aortic stenosis consistent with indications approved by the Food & Drug Administration.

Regarding the first point, the ACC has expressed concern in the past that CMS focuses disproportionately on time in contrast to magnitude estimation, survey data, and expert clinical experience. Elsewhere in the proposed rule the Agency says it would not be appropriate to develop RVUs based solely on time since intensity is also an element of work. The ACC urges CMS to consistently incorporate intensity, magnitude estimation, survey data, expert clinical experience, and extant data (when available) to avoid payment disparities in the *relative valuation* payment system rather than relying on arbitrary calculations based on time to derive RVUs that are almost universally lower than those developed through the RUC process.

Myocardial Positron Emission Tomography (PET)

CPT code 78492 was identified via the High-Volume Growth screen with total Medicare utilization over 10,000 which increased by at least 100% from 2009 through 2014. The RUC referred this code to the CPT Editorial Panel to undergo substantive descriptor changes to reflect newer technology aspects such as wall motion, ejection fraction, flow reserve, and technology

updates for hardware and software. The CPT Editorial Panel approved deletion of a Category III code, addition of six Category I codes, and revision of three codes to separately identify component services included for myocardial perfusion and metabolic imaging using positron emission tomography.

Significant comments on work RVU proposals follow for this family of codes, but an even more impactful aspect of CMS proposals are practice expense inputs. Under the proposed rule, reimbursement for myocardial PET multiple perfusion services would be reduced by roughly 72 percent next year. Other services in the family also face cuts of alarming scale. **The ACC is concerned that reductions of this scale threaten the viability of the service in the physician office setting, will limit patient access to this important imaging modality, particularly in rural and underserved areas, lead to poorer outcomes for patients, and increase beneficiary and health care system costs.** These reductions are presented in Table 1 below.

Table 1

Code	Short Descriptor	2019 Work RVU	2020 Work RVU	2019 NF PE RVU	2020 NF PE RVU	2019 NF Payment	2020 NF Payment	Non-fac. Δ	% Δ
78459	Myocardial PET Metabolic	1.50	1.25	31.77	5.54	$1,201.21	$247.94	-$953.27	-79%
78X29	Myocardial PET Metabolic+CT	NA	1.40	NA	9.94	NA	$412.87	NA	
78491	Myocardial PET Perfusion	1.50	1.00	31.77	6.21	$1,201.21	$263.10	-$938.12	-78%
78X31	Myocardial PET Perfusion+CT	NA	1.11	NA	10.58	NA	$425.14	NA	
78492	Myocardial Multiple PET Perfusion	1.87	1.74	31.77	7.81	$1,214.91	$348.63	-$866.28	-71%
78X32	Myocardial Multiple PET Perfusion+CTs	NA	1.84	NA	14.21	NA	$583.58	NA	
78X33	Myocardial PET Perfusion+Metabolic	NA	1.71	NA	11.05	NA	$465.20	NA	
78X34	Myocardial PET Perfusion+Metabolic+CTs	NA	1.90	NA	19.95	NA	$793.26	NA	
	*Contractor payment for technical component varies by location but is estimated here to be $1145 based on 2017 weighted claims data. **Payment changes are not available for the newly defined codes, but reductions are similarly driven by the difference in the nonfacility PE component from the current $1145.								

Myocardial PET is a noninvasive nuclear study that provides information about both the blood supply to the heart muscle and the metabolic activity of the heart. PET uses radionuclides to produce pictures of the heart. These studies can outline the heart muscle that is not getting adequate blood flow due to blockage in the arteries of the heart. These studies can also show the heart muscle that has been scarred or damaged from past heart attacks. With this information, cardiologists can accurately decide which patients have the potential to benefit from

revascularization and which patients do not, producing better outcomes (Patel) and overall savings for the healthcare system in patients carefully selected for intermediate pretest likelihood of coronary artery disease (Merhige).

When compared with other studies, PET demonstrates high accuracy using lower radiation exposure (Danad) for diagnosis of myocardial ischemia and is particularly successful in diagnosing microvascular heart disease in women (Taqueti) and obese patients (Bajaj). Myocardial PET is being used to diagnose cardiac sarcoidosis (Osborne) and implanted cardiac device infections (Chen), and studied for its usefulness in diagnosing cardiac amyloidosis—a disease that typically is not properly diagnosed until the condition becomes severe and life-threatening.

Accordingly, the ACC recommends CMS defer implementation of direct practice expense inputs in this rulemaking cycle and set nonfacility PE RVUs at the 2018 paid claims weighted average while additional information is collected. Reductions on this scale would be too disruptive to get wrong. The ACC supports the work of the RUC to collect and review direct PE pricing information but is now seeing additional pricing documentation from members during the public comment period that suggests the payment amounts CMS proposes based on that information would undervalue the technical component. A key example of that is the price of the machine, an item members identified as priced too low compared to what the price they paid in several instances. Other costs were felt to be missing or mispriced as well.

Should refinement for future rulemaking still produce significant cuts, it would mitigate disruption to practices and patient access if CMS phased-in resulting payment reductions. Specifically, CMS should view reductions from carrier- or contractor-priced codes through the phase-in as articulated in Section 220 of the "Protecting Access to Medicare Act of 2014" (P.L. 113-93) which allows for a two-year phase-in of payment reductions that exceed 20 percent. Without stability and a sense of where reimbursement will be for these services, patients will lose the benefits myocardial PET offers. Should practices be unable to cover costs in the short term some could even go bankrupt given the scale of investment necessary. If practices are unable to predict stability in the long term, they may take steps to unwind investments already made or planned for the future.

Practice Expense

Technical component payment rates for myocardial PET are set by Medicare Administrative Contractors (MACs) through local carrier pricing. It is challenging to discover exactly what amount all MACs pay, but using data from paid claims, a weighted average of $1145 can be calculated. That amount aligns with members' experience. The ACC believes the transition from contractor pricing to fee schedule pricing in the manner proposed by CMS would create disruption and limit patient access to the service such that further scrutiny is warranted.

While the ACC believes the magnitude of proposed payment reductions and short timeline until the final rule warrants pricing based on prior paid claims for CY 2020, it is also important to share what information has been gathered so far. Additional invoices for some pieces of equipment and costs are summarized in Table 2 below for CMS consideration. However, many

members providing pricing documentation voiced concerns about confidentiality required by purchasing contracts. Therefore, relevant invoices are summarized but not attached at this time.

One aspect noted in the Comment column of the table is that the pricing for ER109 is wrong. Reviewing materials submitted to/by the RUC, it seems CMS priced the PET Generator Infusion Cart at $47,052.80. That invoice and price is for the purchase of the "generator" that comes loaded with the radioactive rubidium 82. The infusion cart is the machine that houses the rubidium generator and draws the rubidium tracer doses. An invoice for purchase of an infusion cart has not yet been identified, but several were provided through the RUC previously and now below for the monthly rental fee, the typical, possibly universal, practice setup. Canvassing of nuclear imaging departments at even large, academic institutions produced only invoices for this rental workflow. It is imperative CMS find a way to compensate practices for the costs of the rented infusion cart that are higher than the current pricing for ER109.

Table 2

	Item	Description	Price	Comment
#1	ER110	PET Refurbished Imaging Cardiac Configuration #1	$499,000	
#2	ER110	PET Refurbished Imaging Cardiac Configuration #2	$730,500	Three installments included in this sum.
#3	ER111	PET/CT Imaging Camera Cardiac Configuration #1	$1,383,081	
#4	ER111	PET/CT Imaging Camera Cardiac Configuration #2	$1,339,502	
#5	ER109	PET Generator Infusion Cart #1	$2,000 per month	This is a monthly rental fee rather than a purchase. ER 109 is incorrectly priced using an invoice for the generator itself, not the infusion cart fee. The infusion cart is typically rented.
#6	ER109	PET Generator Infusion Cart #2	$2,000 per month	This is a monthly rental fee rather than a purchase. ER 109 is incorrectly priced using an invoice for the generator itself, not the infusion cart fee. The infusion cart is typically rented.
#7	ER109	PET Generator Infusion Cart #3	$2,450 per month	This is a monthly rental fee rather than a purchase. ER 109 is incorrectly priced using an invoice for the generator itself, not the infusion cart fee. The infusion cart is typically rented.
#8	NEW	Lead PET Cabinet #1	$14,095	Lead-lined cabinets come in varying sizes and thicknesses for dosing, storage, or decay.
#9	NEW	Lead PET Cabinet #2	$22,860	Lead-lined cabinets come in varying sizes and thicknesses for dosing, storage, or decay.

#10	NEW	PET Service Contract #1	$63,050.04 per year	This is a complex machine that will not function if not properly maintained.
#11	NEW	PET Service Contract #2	$99,999.96 per year	This is a complex machine that will not function if not properly maintained.
#12	NEW	PET Service Contract #3	$53,000 per year	This is a complex machine that will not function if not properly maintained.

Deferring implementation of pricing based on direct PE inputs will allow collection of more accurate data at a critical juncture in provision of myocardial PET. Up to this point it has been common for physician practices to purchase refurbished, standalone PET machines. The supply of such machines has greatly diminished even since February when CMS received invoices from the RUC. As a result, practices will consistently be obtaining new cameras that cost more. Practices are also beginning to anticipate a shift to other tracers that have different infrastructure needs. For example, flurpiridaz-18 is currently under regulatory review and will require procedure rooms to have double layers of lead shielding and a bathroom with lead shielding.

Members have also shared—some in great detail—that additional costs for myocardial PET should be considered in pricing. Detailed breakdowns of these cost examples were $495,000 and $336,000, while many noted it is several hundred thousand dollars. It is typical for building infrastructure improvements like enhanced load-bearing support to be necessary to install a PET machine. Other infrastructure improvements including lead-lining in the walls are required by the Nuclear Regulatory Commission. Separate cooling systems dedicated to the machine are required. Payment rates that fail to account for the startup and maintenance costs necessary to provide high-quality imaging services to sick patients will further disadvantage practices that provide myocardial PET. This is another element the ACC believes can only be thoughtfully considered with additional time, delay of PE implementation, and maintenance of 2018 pricing based on paid claims data.

A different aspect of pricing which CMS could readily modify is its proposal of a 90% utilization rate for both PET and PET/CT equipment. CMS has not based this decision on data nor asked the specialty societies if any information was available. As a point of information, the FDA requires the manufacturers of rubidium generators to track aspects of the delivery of this radiotracer. One of the data points collected each day from each facility is the number of patients imaged with rubidium 82 from each of their generators. These data show an overall average of 4.5 patients imaged per facility per day. The ACC can also share medical specialty expertise that hospitals can perform cardiac PET or PET-CT and oncology PET or PET-CT procedures that have the same or similar resources (shared PET or PET-CT equipment and personnel). That is not the case in the physician office. The PET and PET-CT scanners and personnel in cardiology practices are typically, more than 50% of the time, dedicated for cardiac PET only. Experts that perform cardiac PET and PET-CT in the physician office setting confirm that a 50% utilization would be a more accurate utilization that is based on data and not CMS's inaccurate assumption. **The ACC urges CMS to use the 50% utilization rate on both the PET and PET-CT equipment.**

CMS proposes not to price the "Software and hardware package for Absolute

Quantitation" as a new equipment item, since the submitted invoices included a service contract and a combined software/hardware bundle with no breakdown of individual pricing. Based on the lack of specific pricing data, CMS believes that this software is more accurately characterized as an indirect PE input that is not individually allocable to an individual patient for a service.

It is incorrect for CMS to propose that the software should be removed. Historically, nuclear medicine hardware must have software to run them or they do not work. The same is true for CT and MRI. To analyze myocardial blood flow, one must have both the hardware and software. Likewise, it is the same with ECGs; the equipment comes with software or one cannot run it. **The ACC urges CMS to price the software and hardware package for absolute quantitation as recommended. Separating the software and hardware would render this system inoperable.** The ACC and other societies will work with the RUC to submit separate invoices for the software and the hardware as they become available.

Multiple Proposed Values

Commenting on the proposal for this family of services is difficult because different values are published in different places of the proposed rule. For six of the nine codes in this family different work RVUs are indicated in the text of the proposed rule, Table 20: Proposed CY 2020 Work RVUs for New, Revised and Potentially Misvalued Codes, and Addendum B. The ACC comments focus on the proposed values included in Addendum B.

CMS's proposed values for these existing and new bundled codes will create significant relative value rank order anomalies between lower technology nuclear medicine planar imaging if implemented. **The ACC urges CMS to carefully reconsider the RUC recommended work RVUs**. Two surveys and several pre-facilitation workgroups over multiple RUC meetings were necessary to develop these cogent recommendations that maintain relativity among and across code families. CMS should consider the incremental work between nuclear medicine planar imaging, compared to SPECT with or without CT imaging and compared to PET with or without CT imaging. The work of this technology builds through the code family, yet the CMS values place some of the higher levels of PET in with planar work, which does not make sense clinically. Looking beyond nuclear imaging comparisons, some of the proposed values in the family would be lower than the work RVU proposed for a Level 3 existing patient office visit.

Change in Physician Work

CMS proposes to decrease the work RVUs for all the Myocardial PET codes. **In doing so, the Agency ignores the fact that the physician work has changed for these services.** Myocardial PET imaging has evolved in the past two decades. Changes in instrumentation, computer processing, and software since the mid 1990's allow extraction of greater clinically valuable information on metabolic, perfusion and function. Of note, when these legacy PET services were originally developed, the technology to perform

wall motion or ejection fraction for myocardial PET perfusion did not exist—these new services now include this work. These changes have enhanced the acquisition, processing, quality control, and interpretation while also adding new variables for analysis and review by the physician or qualified healthcare professional.

Vigorous discussion occurred at several pre-facilitation committees and the RUC regarding the prior times being less reliable due to the age of the prior survey and the lower number of survey respondents and lower number of available sites performing PET during that time period. The current times for 78492 reflect a weighted average time, and none of the existing codes divide time in the preservice, intraservice, and postservice, reflecting their age and inaccuracy.

CMS proposals also disregard prior relative nuclear medicine services that have CMS approved survey values such as CPT code 78453 for single myocardial planar perfusion imaging with a work RVU of 1.00 and 78454 for multiple myocardial planar perfusion imaging with a work RVU of 1.34.

Total Time Ratio

The invalid methodology of a total time ratio used by CMS to propose a work RVU for CPT code 78491 corrupts the entire proposal for this family of services. Since all the other recommendations in this family are then built off the proposed value for 78491, every decision after that is flawed. It is both the Agency's and the RUC's longstanding position that treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. In many scenarios, CMS selects an arbitrary combination of inputs to apply, including: total physician time, intra-service physician time, "CMS/Other" physician times, Harvard study physician times, existing work RVUs, RUC-recommended work RVUs, work RVUs from CMS-selected crosswalks, work RVUs from a base code, etc. This selection process has the appearance of seeking an arbitrary value from the vast array of possible mathematical transformations, rather than seeking a valid clinically relevant relationship that would preserve relativity.

Valuing the Increment

In developing proposed RVUs for these services, CMS only relies on the survey data to use the incremental difference between service within this family. The proposed recommendations are not valid because the work RVUs are arrived at solely via a calculation and are not based on survey data nor directly crosswalked to any service. CMS uses values for single perfusion myocardial PET code 78491 to base all the incremental proposed values, regardless of the multifaceted type of PET studies: metabolic or perfusion, number of studies, combination of studies and with or without CT transmission scan. Not comparing "apples to apples" renders the comparison useless. **Valuing the increment inaccurately treats all components of the physician time as**

having identical intensity and is incorrect. CMS should carefully reconsider the clinical information justifying the changes in physician work intensity provided by the RUC.

78459 PET Metabolic – Single Study

CMS disagrees with the RUC recommendation to increase the work RVU to 1.61 based on the survey 25th percentile for CPT code 78459. CMS's proposal overlooks the change in physician work discussed above, that this service is different, instead stating that because of the reduction in time the recommended value is overestimated. CMS proposes a work RVU of 1.25 for CPT code 78459 by applying the increment between 78459 and the myocardial PET perfusion study code 78491. However, with the various proposed work RVUs for this code, it is unclear how this increment is obtained, varying from 0.05 to 0.25. CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU. Concerns with that approach are addressed in the preliminary comments for this family of services.

A work RVU of 1.25 vastly underestimates the physician work required to perform this service. The survey 25th percentile work RVU of 1.61 appropriately accounts for the work required to perform CPT code 78459. This is a PET scan that instead of examining blood flow, as with the perfusion PET, examines metabolism using a tracer, such as glucose. CPT code 78459 requires slightly more physician work than single perfusion myocardial PET code 78491 (RUC recommended work RVU = 1.56) because the metabolic codes examine glucose uptake by the myocardium. The heart is a peculiar organ, as its primary energy source is fatty acid, not glucose like the brain and skeletal muscle. Therefore, the physician needs certain metabolic conditions to be met at the time of the tracer injection for glucose levels and patients must adhere to a specific diet prior to the injections. The metabolic scans are more interactive to ensure a quality uptake scan occurs. The RUC compared the surveyed code to the key reference services multiple perfusion SPECT code 78452 (work RVU = 1.62 and total time of 40 minutes) and limited PET code 78811 (work RVU = 1.54 and total time of 40 minutes) and noted that CPT code 78459 requires less total time but is more intense and complex to perform, thus, appropriately valued similarly to the reference services. For additional support, the RUC also compared the surveyed code to MPC code abdomen and pelvis code 74176 (work RVU = 1.74 and total time of 32 minutes). **The ACC urges CMS to use valid survey data from the physicians who perform this service and accept a work RVU of 1.61 for CPT code 78459.**

78X29 PET Metabolic – Single Study with CT

CMS disagrees with the RUC recommendation of 1.76 work RVUs based on the survey 25th percentile for CPT code 78X29. CMS proposes a work RVU of 1.40 for CPT code 78X29 by applying the increment between 78X29 and the myocardial PET perfusion study code 78491. However, with the various work RVUs it is unclear how this increment is obtained, varying from 0.20 to 0.40.

CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU. Concerns with that approach are addressed in the preliminary comments for this family of services.

A work RVU of 1.40 vastly underestimates the physician work required to perform this service. The survey 25th percentile work RVU of 1.76 appropriately accounts for the work required to perform CPT code 78X29. The RUC confirmed that CPT code 78X29, which includes CT, appropriately requires 3 more minutes intra-service time and 2 more minutes immediate post-service time than the myocardial PET without CT (78459). Likewise, the recommended work RVU for the *with and without CT* demonstrates the appropriate relativity. The RUC compared the surveyed code to the second key reference service 93351 for stress echocardiography (work RVU = 1.75 and total time of 40 minutes) noting that both services require similar physician work, time and intensity to perform and thus should be valued similarly. For additional support, the RUC also compared the surveyed code to similar service 70552 for brain MRI with contrast (work RVU = 1.78 and total time of 32 minutes). **The ACC urges CMS to use valid survey data from the physicians who perform this service and accept a work RVU of 1.76 for CPT code 78X29.**

78491 PET Perfusion – Single Study

CMS disagrees with the RUC recommendation of 1.56 work RVUs for CPT code 78491 based on the survey 25th percentile. CMS's proposal would ignore a change in physician work and that this service is different than previously described, instead stating that because of the reduction in time the recommended value is overestimated. CMS proposes a work RVU of 1.00 based on a time ratio (the recommended 30 minutes divided by the current 45 minutes multiplied by the current work RVU of 1.50, which results in a work RVU of 1.00). CMS references that the work RVU falls between CPT code 78278 for gastrointestinal blood loss imaging (work RVU = 0.99) and CPT code 10021 for fine needle aspiration biopsy (work RVU = 1.03).

The total time ratio calculation is not an accepted methodology to examine and value this service. Valuing CPT code 78491 this way debases the rest of the proposed codes in this family, on which CMS bases the proposed values. A work RVU of 1.00 vastly underestimates the physician work required to perform this service. The survey 25th percentile work RVU of 1.56 appropriately accounts for the work required to perform CPT code 78491. The RUC compared the surveyed code to the key reference services 78452 for multiple perfusion SPECT (work RVU = 1.62 and total time of 40 minutes) and 78811 for limited PET (work RVU = 1.54 and total time of 40 minutes) and noted that CPT code 78491 requires less total time but is more intense and complex to perform. CPT code 78491 is slightly more intense than the key reference codes because it involves PET isotopes, whereas CPT code 78452 does not and is performed on complex patients that are high risk with multiple previous stents and CABGs. Thus, appropriately valued similarly to the reference services and maintains the relativity among these services. For additional support, the RUC also compared the surveyed code to MPC code

74176 for CT abdomen and pelvis without contrast (work RVU = 1.74 and total time of 32 minutes).

CPT code 78491 requires much more physician work than the two codes CMS references, 78278 and 10021. As noted earlier, CMS compares planar services such as CPT code 78278 that is a series of 2D planar images that do not require any manipulation; there is no 3D component to 78278, nor are there other organs and analytics to review and consider during the study. CPT code 78278 is clearly less work than 78491 as well as several other of the new cardiac PET codes. CMS should review CPT code 78453 myocardial planar perfusion imaging (work RVU = 1.00) as noted earlier in this discussion. This is a 2D study, much like comparing the work to review an X-Ray, compared to a 3-D CT study and would create a clear rank order problem to the medical community if CMS does not reconsider the RUC recommended RVUs, which are consistent with the time increments and the varying work for these higher technology services. The technology alone of analysis and review of the many images makes it clear that it would be inappropriate to value this service at 1.00 as CMS proposes. **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 1.56 for CPT code 78491.**

78X31 PET Perfusion – Single Study with CT

CMS disagrees with the RUC recommended work RVU of 1.67 for CPT code 78X31, which is based on the survey 25th percentile. CMS proposes a work RVU of 1.11 by applying the increment between RUC recommendations between CPT code 78491 and this code, an increment of 0.11, to the proposed value of 1.00 for CPT code 78491. CMS notes that the proposed value falls between CPT codes 95977 *for electronic analysis of implanted neurostimulator* (work RVU = 0.97) and CPT code 93284 for in person ICD programming (work RVU = 1.25).

CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU. Additionally, CMS's statement that valuing CPT code at the survey 25th percentile would place this among the highest value with other XXX global services with similar times is false. There are at least 50 codes with similar times and higher work RVUs than the RUC recommendation for CPT code 78X31.

A work RVU of 1.11 vastly underestimates the physician work required to perform this service. The survey 25th percentile work RVU of 1.67 appropriately accounts for the work required to perform CPT code 78X31. The RUC confirmed that CPT code 78X31, which includes concurrent CT, appropriately requires 2 more minutes intra-service time than the myocardial PET perfusion single study without CT (78491). Likewise, the recommended work RVU for the with and without CT demonstrates the appropriate relativity. The RUC compared the surveyed code to the key reference services 78814 for limited area PET with CT attenuation (work RVU = 2.20 and total time of 60 minutes) and noted that the survey code requires less physician time. The RUC also compared the service to second key reference code 78072 for parathyroid planar imaging with SPECT

and CT (work RVU = 1.60 and total time of 30 minutes) and noted that CPT code 78X31 is slightly more intense and complex to perform. CPT code 78X31 requires less physician time and work than top key reference service 78814 and slightly more physician time and work than the second key reference service 78072. Thus, appropriately valued compared to the reference services. For additional support, the RUC also compared the surveyed code to similar code 53855 for Insertion of a temporary prostatic urethral stent (work RVU = 1.64 and total time of 32 minutes).

CPT code 78X31 requires much more physician work than the two services CMS referenced, 95977 and 93284. One of the CMS proposed comparators for services is for analysis of a neurostimulator and the other for programming of a cardiac device; however, neither is an imaging study with complex anatomy. CPT code 78X31 involves selection of a radiopharmaceutical with distribution correlated with anatomy involving many images through slice and cine review. Additionally, analysis of ejection fraction, wall motion is typical in conjunction with the medical symptoms and medications for the patient. The RUC believes these services are not a good reference point and suggest that CMS reconsider the RUC comparators as well as other more appropriate nuclear medicine procedures that incorporate the regulatory, perfusion, and the computation aspects of these services. A more relevant reference service comparator noted above is CPT code 78072 SPECT-CT parathyroid (work RVU = 1.60). At least CPT code 78072 has the aspects of CT and 3D and only missing the PET complexity, additionally the times are slightly less therefore supporting the RUC recommended times and values. **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 1.67 for CPT code 78X31.**

78492 PET Perfusion – Multiple Studies

CMS disagrees with the RUC recommendation of 1.80 work RVUs based on the survey 25th percentile for CPT code 78492. CMS proposes a work RVU of 1.74 for CPT code 78492 by applying the increment between myocardial PET perfusion single study code 78491 and the myocardial PET perfusion multiple studies code 78492. However, with the various work RVUs it is unclear how this increment is obtained, varying from 0.13 to 0.63. Regardless, CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU. A critique regarding that approach is included in the preliminary comments for this family of services.

It is unclear why CMS would disregard the survey data only to propose a value 0.06 RVUs lower. The survey 25th percentile work RVU of 1.80 appropriately accounts for the work required to perform CPT code 78492. CPT code 78492 is a myocardial PET perfusion study comparing perfusion immediately following exercise and at rest. The RUC compared the surveyed code to the key reference services 78452 for multiple perfusion SPECT (work RVU = 1.62 and total time of 40 minutes) and 78812 for PET from skull base to mid-thigh (work RVU = 1.93 and total time of 50 minutes) and noted that CPT code 78492 requires less total physician time but is slightly more intense and complex to perform, thus, appropriately valued compared to the reference services. For

additional support, the RUC also compared the surveyed code to MPC code 93351 for stress echocardiography (work RVU = 1.75 and total time of 40 minutes) and similar service code 70552 for brain MRI with contrast (work RVU = 1.78 and total time of 32 minutes). **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 1.80 for CPT code 78492.**

78X32 PET Perfusion – Multiple Studies with CT

CMS disagrees with the RUC recommendation of 1.90 work RVUs for CPT code 78X32 based on a crosswalk to 64617 for c*hemodenervation of larynx muscle(s)* (work RVU = 1.90), since the survey 25th percentile work RVU of 2.00 was slightly high for the addition of concurrent CT in comparison with CPT code 78492 PET, perfusion, multiple studies without CT. CMS proposes a work RVU of 1.84 for CPT code 78X32 by applying the increment between myocardial PET perfusion single study code 78491 and the myocardial PET perfusion multiple studies code with CT, 78X32. However, with the various work RVUs it is unclear how this increment is obtained, varying from 0.34 to 0.84. The RUC also questions why CMS comes to a value comparing 78491 and 78X32 as this examines a PET perfusion *single study* to a PET perfusion *multiple study with CT*. There are multiple facets to each of these codes and a simple increment for the two codes chosen is not comparative. Regardless, CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU.

It is unclear why CMS would disregard a valid direct crosswalk only to propose a value 0.06 RVUs lower than the RUC recommendation. The RUC recommended a work RVU of 1.90 appropriately accounts for the work and time required to perform code 78X32. Therefore, the crosswalk maintains the rank order and relativity among this family of services.

The RUC compared the surveyed code to the key reference services 75574 for CT angiography of the heart (work RVU = 2.40 and total time of 50 minutes) and 78814 for limited area PET with CT attenuation (work RVU = 2.20 and total time of 60 minutes) and noted that CPT code 78X32 requires less total physician work and time to perform. Thus, appropriately valued compared to the reference services. For additional support, the RUC referenced similar service 56821 for simple repair of superficial wounds (work RVU = 1.98 and total time of 37 minutes). **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 1.90 for CPT code 78X32.**

78X33 PET Perfusion Single Study + Metabolic Study

CMS disagrees with the RUC recommendation of 2.07 work RVUs for CPT code 78X33 based on the survey 25th percentile work RVU. CMS states they that this work RVU is greater than those of all other services of similar intra-service time values suggests that it is an overestimate. CMS proposes a work RVU of 1.71 for CPT code 78X33, based on an incremental methodology by applying the RUC recommended increment between 78491

and CPT code 78X33. However, with the various work RVUs it is unclear how this increment is obtained, varying from 0.51 to 0.71. The RUC also questions CMS's comparison of codes 78491 and 78X33 as this code examines a PET *perfusion single study and metabolic study* to a PET perfusion *multiple study with CT*. There are multiple facets to each of these codes and a simple increment for the two codes chosen is not comparative. Lastly, there are over 60 services with similar intra-service time with an XXX global period that have higher work RVUs than the 2.07 recommended. Likewise, reviewing a list of codes without providing any clinical basis on why the Agency believes this service is overestimated is unsubstantiated. Regardless, CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU.

A work RVU of 1.71 underestimates the physician work required to perform this service. The survey 25th percentile work RVU of 2.07 appropriately accounts for the work required to perform CPT code 78X33. CPT code 78X33 includes the myocardial PET perfusion and metabolic studies. This service is intense and is performed on complicated patients, with injection fractions less than 30% and multi-vessel coronary disease, where the physician is trying to decide if there is enough tissue that is worth re-vascularizing. The physician tries to match the perfusion flow to the metabolism to look for areas of mismatch where there is decreased flow but retained increased metabolism.

The RUC compared the surveyed code to the key reference services 75574 for CT angiography of the heart (work RVU = 2.40 and total time of 50 minutes) and 78815 for PET with CT attenuation from skull base to mid-thigh (work RVU = 2.44 and total time of 65 minutes) and noted that CPT code 78X33 requires less total physician time and work but is slightly more intense and complex to perform, thus, appropriately valued lower compared to the reference services. For additional support, the RUC also compared the surveyed code to similar service CPT code 56821 for colposcopy with biopsy (work RVU = 12.05 and total time of 45 minutes). **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 2.07 for CPT code 78X33.**

78X34 PET Perfusion Single Study + Metabolic Study with CT

CMS disagrees with the RUC recommendation of 2.26 work RVUs for CPT code 78X34 based on a crosswalk to CPT code 78X34 to CPT code 71552 for chest MRI without contrast (work RVU = 2.26 and 7.5 minutes evaluation pre-time, 24 minutes intra-service time and 10 minutes immediate post-service time). CMS states that this work RVU is greater than those of all other services of similar intra-service time values suggests that it is an overestimate. CMS proposes a work RVU of 1.90 for CPT code 78X34 by applying the increment between myocardial PET perfusion single study code 78491 and the myocardial PET perfusion single study and metabolic study with CT code with CT 78X34. However, with the various work RVUs it is unclear how this increment is obtained, varying from 0.50 to 0.70. The RUC also questions why CMS comes to a value comparing 78491 and 78X34 as this examines a PET *perfusion single study* to a PET *perfusion single study and metabolic multiple study with CT*. There are multiple facets to

each of these codes and a simple increment for the two codes chosen is not comparative. Lastly, there are about 50 services with similar intra-service time with an XXX global period that have higher work RVUs than the 2.26 recommended. Likewise, reviewing a list of codes without providing any clinical basis on why the Agency believes this service is overestimated is unsubstantiated. Regardless, CMS continues to apply an invalid method, using an increment approach with no direct crosswalks and void of any clinical input solely to produce a lower work RVU.

It is unclear why CMS would disregard a valid direct crosswalk. The RUC recommended a work RVU of 2.26 appropriately accounts for the work and time required to perform code 78X34. Therefore, the crosswalk maintains the rank order and relativity among this family of services.

The RUC compared the surveyed code to the key reference services 75561 for cardiac MRI (work RVU = 2.60 and total time of 65 minutes) and 78815 for PET with CT attenuation from skull base to mid-thigh (work RVU = 2.44 and total time of 65 minutes) and noted that CPT code 78X34 requires less total physician work and time to perform. Thus, appropriately valued compared to the reference services. **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 2.26 for CPT code 78X34.**

78X35 Absolute Quantitation of Myocardial Blood Flow

CMS disagrees with the RUC recommended work RVU of 0.63 for CPT code 78X35 based on the survey 25th percentile. CMS believes a comparison to other codes with a global period of ZZZ suggests that this is somewhat overvalued. CMS based values for the other codes in this family on their relative relationships to CPT code 78491; for that code the Agency's analysis indicates that a reduction from the RUC value of roughly 1/3 is appropriate, based on a ratio of the decrease in total time to the current work RVU. Therefore, CMS applied a similar reduction of 1/3 to the RUC recommended work RVU of 0.63 to arrive at an RVU of approximately 0.42. CMS states they believe this work RVU is validated by noting that it is bracketed by CPT codes 15272 for additional application of skin substitute graft (work RVU = 0.33) and 11105 for punch biopsy of skin (work RVU = 0.45).

Proposing a one third reduction stemming from the portion CMS proposed to reduce the other codes of this family based on a compounded initial proposed flawed methodology further renders the proposed value for 78X35 unusable.

It is unclear why CMS disregards valid survey data. The survey 25th percentile work RVU of 0.63 appropriately accounts for the work required to perform CPT code 78X35. This service involves a complex integration of clinical information — it is a dynamic flow study performed real-time with an electrocardiogram. The physician must assess the flow data and ensure the quality is good enough to interpret and report since it will make major clinical differences. A variety of regions of interest are reviewed and a variety of curves are matched for differences between rest and stress and the physician must attempt

to adjudicate those values in three different vascular beds. This is not simply the reporting of a number nor physician validation of a computer-generated number.

The RUC compared the surveyed code to the key reference services 78496 for cardiac blood pool imaging, (work RVU = 0.50 and intra-service/total time of 19 minutes) and 93567 for supravalvular aortography injection during cardiac catheterization (work RVU = 0.97 and intra-service/total time of 15 minutes) and noted that CPT code 78X35 requires similar physician work and time to perform. Thus, appropriately bracketed by the reference services. The RUC noted that the survey 25th percentile work RVU of 0.63 falls appropriately in the broader range relative to many other services. For additional support, the RUC referenced MPC codes 51797 for voiding pressure studies, (work RVU = 0.80 and total time of 15 minutes) and 96411 for intravenous chemotherapy administration (work RVU = 0.20 and total time of 7 minutes). **The ACC urges CMS to use valid survey data from physicians who perform this service and accept a work RVU of 0.63 for CPT code 78X35.**

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study;	1.25*	1.61
78X29	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study; with concurrently acquired computed tomography transmission scan	1.40*	1.76
78491	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction~~s~~(s), when performed); single study, at rest or stress (exercise or pharmacologic)	1.00	1.56
78X31	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	1.11	1.67

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
78492	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); multiple studies at rest and stress (exercise or pharmacologic)	1.74*	1.80
78X32	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	1.84*	1.90
78X33	Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (eg, myocardial viability);	1.71*	2.07
78X34	Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	1.90*	2.26
78X35	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography, rest and pharmacologic stress (List separately in addition to code for primary procedure)	0.42	0.63

**Different work RVUs indicated in Table 20 and Addendum B versus the text of the Proposed Rule*

Pericardiocentesis and Pericardial Drainage

For CPT 2020, the CPT Editorial Panel replaced four codes with four new codes to describe pericardiocentesis drainage procedures to differentiate by age and to include imaging guidance. CPT Code 33015, which was originally identified by the RUC's Relativity Assessment Workgroup for review due to its negative IWPUT. Code 33015 is

a 090-day global service and the three codes that it is being bundled into, 3X001-3X003, will all be 000-day global services. CMS' comparison of 33015's erroneous physician time to the newly bundled codes is severely misguided.

CPT code 33015 is being replaced with bundled codes 3X001-3X003 which also newly include imaging guidance. CPT code 33010 *Pericardiocentesis; initial* is being deleted and will be reported using new code 3X000 which also newly bundles image guidance. While CPT code 33010 was on the RUC's first Five-Year Review agenda, no action was taken. The work RVU and times are from the Harvard study. Since that time, other similar services that involve a lower amount of physician work have been reviewed by the RUC and CMS, and now have higher values, for example top key reference code 32557 for percutaneous pleural drainage (work RVU = 3.12).

At the January 2019 RUC meeting, the RUC reviewed compelling evidence that the current pericardiocentesis and pericardial drainage codes are misvalued. Code 33015 currently has a very general code descriptor, was valued under the Harvard study and has a negative IWPUT. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is Harvard, implying that the time was merely extrapolated and not measured directly.** Since code 33010 and 33015 were last valued, there has been a change in the patient population; patients who receive these services have become more complex, acute, and heterogeneous. These used to typically be patients who had chronic effusions during renal failure and dialysis. Today this is a heterogenous population, including malignancies, infections, iatrogenic effusions with tamponade, and other complications of implanted therapeutic devices like pacemakers and ICDs. The RUC agreed that these services are likely misvalued based on several compelling evidence criteria: incorrect assumptions in prior valuation, rank order anomaly and a change in patient population.

Pericardiocentesis and pericardial drainage procedures are performed largely for the life-threatening condition of cardiac compression by fluid or blood (cardiac tamponade). Further, with the burgeoning development and application of many transcatheter intracardiac procedures such as atrial fibrillation ablation, implantable cardioverter defibrillator insertion and transcatheter valve replacements these procedures are emergencies related to cardiac injury. As to the procedures themselves, they include the hazard of iatrogenic cardiac injury or failure to resolve the tamponade either of which can (and sometimes does) lead to death within seconds or minutes.

3X000

For CPT Code 3X000, CMS disagrees with the RUC recommended work RVU of 5.00 and proposes a work RVU of 4.40 based on a direct work RVU crosswalk to CPT code 43244 for esophagogastroduodenoscopy (work RVU= 4.40, intra-service time of 30 minutes, total time of 81 minutes). CPT code 3X000 is one of the more intense procedures that interventional cardiologists perform, with two of the most common complications being either lacerating the coronary artery or puncturing the right ventricle,

either of which can be fatal. CMS' proposed intensity reduction, relative to the RUC recommendation, would make this service out of rank order with other services in the MPFS including CMS's proposed crosswalk code. An upper endoscopy procedure, even though the typical patient for 43244 presents with hematemesis, involves less work and less risk than performing 3X000 and therefore is not an appropriate crosswalk. Although both services involve identical intra-service time, the survey code is clinically a much more intense service to perform.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to reference codes 45385 for flexible colonoscopy (work RVU= 4.57, intra-service time of 30 minutes, total time of 68 minutes) and code 31276 for nasal/sinus endoscopy (work RVU= 6.75, intra-service time of 45 minutes, total time of 98 minutes). **The ACC urges CMS to accept a work RVU of 5.00 for CPT code 3X000.**

3X001

For CPT Code 3X001, CMS disagrees with the RUC recommended work RVU of 5.50 and proposes a work RVU of 4.62 based on a direct work RVU crosswalk to CPT code 52234 for cystourethroscopy, (work RVU= 4.62, intra-service time of 30 minutes, total time of 79 minutes). CPT code 52234 is not an appropriate crosswalk code as this is a planned procedure, whereas code 3X001 is typically emergent and more intense as the patient has acute hemodynamic instability.

Furthermore, the increment of CMS' proposed values between codes 3X000 and 3X001, 0.22 does not align with the relative increased difficulty and additional work involved in performing 3X001. CPT code 3X000, while still relatively urgent to perform, is a planned procedure. Additionally, CPT code 3X001 includes all work of CPT code 3X000, with the addition of suturing an indwelling catheter in place as well as the work of managing that catheter. With the drain left in place, the physician must provide additional documentation and additional instructions for care of the drain relative to 3X000. The IWPUT of CMS' proposed value for 3X001 is only 5 percent higher, which is insufficient.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to reference code 93456 for diagnostic coronary catheterization (work RVU= 5.90, intra-service time of 40 minutes, total time of 108 minutes) and code 31276 for nasal/sinus endoscopy, (work RVU= 6.75, intra-service time of 45 minutes, total time of 98 minutes). **The ACC urges CMS to accept a work RVU of 5.50 for CPT code 3X001.**

3X002

For CPT Code 3X002, CMS disagrees with the RUC recommended work RVU of 6.00 and proposes a work RVU of 5.00 based on the survey 25th percentile value. The typical patient for 3X002 is a small child. There is less space for the fluid to accumulate in a

small child, the target-zone is smaller for the needle, and therefore the procedure is more intense. Also, the patient is typically more complex relative to the typical patient for the other services in this new code family. The IWPUT of CMS' proposal for 3X002, 0.1161, is nearly identical to the IWPUT of CMS's proposed value for the relatively less intense service to perform 3X000, which would create a rank order anomaly with respect to intensity. The deleted code 33015 (which is being bundled into 3X002) was last evaluated by the RUC and CMS in 1995.

When the RUC reviewed the estimated physician work values, the Committee determined that the survey 25th percentile work RVU of 5.00 would undervalue the work of the service and the median work RVU of 7.00 overvalues the work required to perform the service. The RUC recommendation was based on a direct work RVU crosswalk from code 31603 for emergency tracheostomy (work RVU= 6.00, intra-service time of 30 minutes, total time of 105 minutes), as both services have identical intra-service time, involve a very similar amount of total time and an identical amount of physician work. The RUC recommendation would also place this pediatric/congenital pericardial drainage in appropriate rank order with the other codes in the family, pericardiocentesis code 33X00 and adult pericardial drainage code 3XX01. The RUC also referenced code 45390 for colonoscopy (work RVU= 6.04, intra-service time of 45 minutes, total time of 83 minutes). **The ACC urges CMS to accept a work RVU of 6.00 for CPT code 3X002.**

3X003

For CPT Code 3X003, CMS disagrees with the RUC recommended work RVU of 5.00 and proposes a work RVU of 4.29 based on the survey 25th percentile value. CMS' proposed value for 3X003 would create a rank order anomaly with 3X000. Although both procedures have distinct attributes, they both involve an identical amount of physician work.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and favorable comparison to reference codes 45385 for colonoscopy (work RVU= 4.57, intra-service time of 30 minutes, total time of 68 minutes) and code 31276 for nasal/sinus endoscopy (work RVU= 6.75, intra-service time of 45 minutes, total time of 98 minutes) which appropriately bracket the RUC recommendation. **The ACC urges CMS to accept a work RVU of 5.00 for CPT code 3X003.**

Intravascular Ultrasound

CPT codes 37252 and 37253 were identified via the Work Neutrality screen for CPT 2016 codes. Any code family that has an increase in work RVUs over 10% of what was estimated is reviewed by the RUC to determine what is occurring to impact claims. Intravascular ultrasound, CPT codes 37252 and 37253 were reviewed at the January 2015 RUC meeting and assumed to be a savings. However, the codes had a 44% increase in work RVUs over the old codes from 2015 to 2016 and the utilization was double from that of the prior coding structure, not considering the radiological activities. Therefore, the RUC recommended to resurvey these services.

37252

CMS disagreed with the RUC recommendation to maintain the current work RVU of 1.80 for CPT code 37252, which was also the survey 25th percentile. CMS is proposing a work RVU of 1.55 based on a crosswalk to CPT code 19084 for breast biopsy (work RVU = 1.55 and 20 minutes intra-service time and 25 minutes of total time). In reviewing CPT code 37252, CMS notes, that in CY 2015 the specialty society stated that bundling this service would achieve savings. However, since 2015 observed utilization for CPT code 37252 has greatly exceeded proposed estimates, thus CMS is proposing to restore work neutrality to the intravascular ultrasound code family to achieve the initial estimated savings.

While there was a reduction in work RVUs for an individual service with the original bundling in 2014, there was an overall increase in utilization offsetting the projected work savings. The increase in utilization came from the concurrent CMS decision to price these services in the non-facility setting and to expand coverage to venous disease. Site of service changes (migrating into the office setting) for these services and change in patient population (venous disease) explain the observed growth. These services are performed approximately 35,000 in the Medicare 2017 estimated utilization data. Likewise, the *Physician and Other Supplier Data for CY 2016* indicates that 11% of the utilization for CPT code 37252 are performed by 10 specific individuals and 18% of the utilization of CPT code 37253 are performed by 10 specific individuals. The claims for these services in the office appear to be highly concentrated in relatively few offices. This compelling evidence explains the growth of these services.

The ACC does not believe that CPT code 37252 requires the same physician work as CPT code 19084. The intra-service time of 20 minutes for CPT code 37252 is different from that of 19084. IVUS assists in medical decision making during the intervention and by many operators is used for problem solving and assessment of adequacy of the intervention, which could result in further intervention. This inherently is more complex than the 20-minute intra-service time of CPT code 19084 where a breast lesion biopsy and clip placement is performed using imaging guidance. The intra-service time for 19084 is a similar process in every patient and is binary, whereby the lesion is biopsied or not. The findings of IVUS, however, can help determine what is the best course of treatment for the patient.

The RUC recommended work RVU of 1.80 for CPT code 37252 is supported by the survey key reference service chosen by physicians who perform this service, CPT code 92978 for endoluminal intravascular ultrasound or optical coherence tomography imaging of coronary vessel or graft (work RVU = 1.80 and intra-service time of 25 minutes). **The ACC urges CMS to accept a work RVU of 1.80 for CPT code 37252.**

37253

For CPT code 37253, CMS disagreed with the RUC recommendation to maintain the work RVU of 1.44, which was also the survey 25th percentile. However, CMS notes the relative difference in work between CPT codes 37252 and 37253 is an interval of 0.36 RVUs. CMS is proposing a work RVU of 1.19 for CPT code 37253, based on the recommended interval of 0.36 fewer RVUs than the proposed work RVU of 1.55 for CPT code 37252.

It appears inconsistent for CMS to only use the survey data to create an incremental difference between these two services. The proposed recommendation is not valid because it is only a calculation and not based on survey data nor directly crosswalked to any service**. The ACC strongly discourages the use of valuing the increment. This inaccurately treats all components of the physician time as having identical intensity and is incorrect. CMS should carefully consider the clinical information justifying the changes in physician work intensity.**

CMS should rely on valid survey data and relative services in the Physician Payment Schedule such as CPT code 92978 for endoluminal intravascular ultrasound or optical coherence tomography imaging of coronary vessel or graft (work RVU = 1.80 and intra-service time of 25 minutes) and 92979 for endoluminal intravascular ultrasound or optical coherence tomography imaging of coronary vessel or graft in an additional vessel (work RVU = 1.44 and 25 minutes intra-service time). The RUC noted that the intensity and complexity to perform these services are similar warranting a similar work RVU. **The ACC urges CMS to accept a work RVU of 1.44 for CPT code 37253.**

Abdominal Aortography

The ACC appreciates that CMS is proposing to retain the RUC recommended work RVU for CPT code 75630. However, CMS has proposed to reduce the RUC recommended work RVU from 1.75 to 1.44 for CPT code 75625. The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS-Other, implying that the time was merely crosswalked some time ago.

75625

For CPT code 75625, the RUC recommended a work RVU of 1.75. CMS disagrees with the RUC recommended work RVU of 1.75 and is proposing a work RVU of 1.44 for code 75625 based on an analysis to the top key reference service (KRS) 75710 for extremity angiography (work RVU = 1.75, 40 minutes intra-service time). CMS proposes a work RVU reduction to 1.44 for CPT code 75625 based on an intra-service time and total-service time ratio with KRS code 75710. The Agency compares the intra-service time ratio between the survey time of 30 minutes and the KRS time of 40 minutes and found a ratio of 25 percent, or a work RVU of 1.31. Additionally, the Agency compares the total-service time ratio between the survey time of 60 minutes and the KRS time of 70 minutes and found a ratio of 14 percent, or a work RVU of 1.51. CMS believes an

accurate value for CPT code 75625 would lie between the range of 1.31 and 1.51 RVUs. This is an invalid methodology to identify an RVU range.

In addition, the Agency chooses code 38222 for diagnostic bone marrow biopsy (work RVU = 1.44, 30 minutes intra-service time) as a crosswalk to support a proposed work RVU of 1.44 that fits within their range. This is a poor code to use as a crosswalk because 1) it is performed by physicians from a different specialty, 2) it does not involve imaging and exposure to radiation, 3) it does not require intra-arterial access or monitoring of hemodynamic parameters, and 4) it is a much lower risk procedure. The choice of code 38222 for a crosswalk is inappropriate because there is no clinical coherence between both codes. One is a vascular interpretive procedure while the other is a sampling procedure.

The ACC disagrees with CMS' methodology to alternatively value CPT code 75625. The ACC urges CMS to use valid survey data and supportive relative reference services when valuing codes. The RUC thoroughly discussed the physician work, time, intensity and complexity required to perform CPT code 75625. It is not the case that the lower intra-service time in CPT code 75625 should result in a lower work value. While the recommended intra-service time for CPT code 75625 as compared to KRS 75710 is lower (30 minutes compared to 40 minutes), the ACC disagrees with the concept that work is decreasing. CMS should use valid survey data and review the actual relativity for all elements (physician work, time, intensity and complexity) when developing work values for services and not foster flawed methodologies and solely focus on time. The ACC recommends CMS implement the work RVU of 1.75 for code 75625 which is the survey 25th percentile.

Remote Interrogation Device Evaluation

CMS chose not to accept the direct practice expense inputs as recommended by the RUC for previously work-only CPT codes 93297 and 93298. Societies provided CMS with thoughtful rationale detailing the way that this family of services is currently used and how contractor priced CPT code 93299 will no longer be necessary when 93297 and 93298 are valued for both work and practice expense. The ACC believes that it is unnecessary to create a G-code to maintain contractor pricing for the service currently provided using 93299. Currently 93299 is meant to serve as the catch-all for both types of 30-day remote monitoring services, but in the decade since these codes were created, it has become clear that implantable cardiovascular monitor (ICM) and implantable loop recorder (ILR) services are very different services and the PE cannot be appropriately captured for both services in a single technical code simply because both cover a 30-day period. CPT code 93297 is related to the remote monitoring of physiological measures obtained from implantable pacemakers and defibrillators related to heart failure that come at an interval of every 30 days. CPT code 93298 refers to subcutaneous wireless remote monitors that provide data at more frequent interval, requiring more clinical staff work.

The ACC was confused by CMS's analysis that, "In our review of these services, we note that the RUC recommendations did not provide a detailed description of the clinical labor

tasks being performed or detailed information on the typical use of the supply and equipment used when furnishing these services." In terms of the clinical labor tasks there was only one clinical activity recommended clinical activity, *perform procedure/service---NOT directly related to physician work time* (CA021). The Clinical activity CA021 indicates that the clinical staff works independently of the physician to provide the service. Granular detail regarding what the clinical staff completes during the intra-service (of service period) clinical activity, *perform procedure/service---NOT directly related to physician work time,* was provided in the PE Summary of Recommendation (SOR) included with the RUC direct practice expense inputs recommendations for these services. It explained that clinical staff educates the patient about the device and transmittal protocols, troubleshoots hardware/connectivity issues, receives and reviews remote transmissions, distributes results, and prepares a report. In addition to this information included in the PE SOR a breakdown of the Electrodiagnostic Technologist work throughout the 30-day reporting period in the text of the RUC recommendation was also provided. It is quoted again below:

> That data indicates that over the course of a month, a technologist interacts with patient monitoring reports 1.63 times a month to process device-generated notifications for 17 minutes, 1.74 times a month to process patient-generated notifications for 19 minutes, and once a month to generate a monthly report for 14 minutes. That is 50 minutes per month for alerts and report work. Additionally, the clinical staff engages with the patient throughout the month to perform education about the device and re-education protocols after the initial enrollment (11 minutes), troubleshoot non-connective monitoring hardware (4 minutes), and request manual transmission(s) to incorporate additional device data into reports (11 minutes). That is 26 minutes per month for patient interaction.
>
> The table below outlines this time:

Activity	**93298/93299**	**93297**
Automated alert transmissions	17	
Technician requested transmissions	11	
Patient-initiated transmissions	19	11
Monthly report	14	14
Education/re-education	11	11
Troubleshooting	4	4
Sum	**76**	**40**

To respond to CMS's request for additional detail, additional information was assembled for both codes to help ensure CMS understands the services and recommendations. As described in the original submission, to obtain objective data for the RUC, societies requested data from a manufacturer of these devices. The minutes for clinical staff time represent the average number of minutes over a 30-day period that a technician was logged on to the manufacturer's remote monitoring server managing the data from a single patient

with an implantable physiologic monitor for each of listed activities.

93297

Many implantable pacemakers and defibrillators now have the additional capability of providing physiologic monitoring to anticipate early warning signs of decompensated heart failure. It is helpful to explain a few aspects of how these devices communicate.

- Devices fall into 1 of 3 categories, those that will trigger an automatic notification when a physiologic parameter is abnormal, those that send a report monthly, and those that do both.
- If a device generates an alert it will be communicated to the manufacturer's servers.
- Each business morning, office practice staff log on to each of the vendors' remote monitoring server to see if any of their patients with an implantable physiological monitor have generated alerts.
- If an alert is received the technician will then prepare a report for the physician to review.
- If a remote monitor ceases communication for any reason during the 30-day window, the technician will contact the patient to troubleshoot and restore communication.
- Patients and family often call the technician with questions about the physiologic monitor, transceiver, and communication of their data. The transceivers unfortunately do not provide feedback to the patient regarding success or failure of a transmission. Therefore, education has become a significant component of the technician's role.
- At the beginning of each 30-day cycle, the physiologic monitor will send a complete report of activity over the previous 30 days. The practice technician will prepare a monthly report for the physician to review. It is at this point that the encounter charge is typically generated.

93298

In order to explain the work involved in remote monitoring for implantable loop recorders (ILR) (also known as subcutaneous cardiac rhythm monitors) it is helpful to explain a few aspects about how these devices communicate:

- When the monitoring process begins, the initial transmission includes the programmed parameters of the ILR, battery status and any recorded arrhythmias.
- Each night over the following 30 days the remote transceiver (located on the patient's bedside table) wirelessly communicates with the ILR. If the ILR has detected any abnormal rhythm or any malfunction with the device it will send an alert back to the manufacturer's servers (automated alert transmission).
- Patients may also trigger the ILR to initiate a recording, which will later be communicated as an alert to the manufacturer when the transceiver communicates with the ILR in the middle of the night (patient-initiated transmission).

- Each morning, office practice staff log on to each of the vendors' remote monitoring server to see if any of their patients with an ILR have recorded any alerts.
- If one of their patients has had an alert the technician then calls the patient and will ask the patient to place the transceiver's wand over the ILR so that the heart rhythm recordings can be downloaded by the practice (technician requested transmission).
- The technician will then prepare a report for the physician to review.
- If a remote monitor ceases communication for any reason during the 30-day window, the technician will contact the patient to troubleshoot and restore communication.
- Patients and family often call the technician with questions about the ILR, transceiver, and communication of their data. The transceivers unfortunately do not provide feedback to the patient regarding success or failure of a transmission. Therefore, education has become a significant component of the technician's role.
- At the beginning of each 30-day cycle, the ILR will send a complete report of activity over the previous 30 days. The practice technician will prepare a monthly report for the physician to review. It is at this point that the encounter charge is typically generated.

The ACC urges CMS to accept the original RUC recommendation of 40 and 76 minutes total clinical labor time for CPT codes 93297 and 93298, respectively.

CMS stated that they are "…seeking additional comment on the appropriateness of CPT code 93296 *Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results* as the reference code." The current recommendation uses 93296 as a simple reference code because it is a similar service insofar as it is a remote interrogation of an electrophysiology device with similarities in terms of information workflow, but the recommended inputs for 93297 and 92398 are based on new data that was not available when the codes were last valued and the recommended PE inputs are in no way a crosswalk to the inputs of 93296. The 90-day service period for 93296 compared to the 30-day service period for 93297 and 93298 does not inform the input values, only the input components.

CMS also requested clarification on the number of patients that are monitored concurrently. Implantable loop recorders generate more alerts than pacemakers or defibrillators because they are implanted in the subcutaneous tissue. Unlike pacemakers and defibrillators which have transvenous leads implanted in the heart, ILRs obtain subcutaneous recordings via electrodes at either end of the device. This wide antenna is susceptible to detecting pectoral muscle stimulation, motion artifact and other interference. This leads to frequent alerts that require careful review. It can often be challenging to determine if an event is due to an arrhythmia. For this reason, it is imperative that each event be reviewed by a physician. A typical arrhythmia center that provides remote monitoring services for its patients will

monitor a panel of patients with pacemakers, defibrillators and ILRs. The number of patients with ILRs being concurrently monitored varies but could range from 50 to 75.

Supply items SK057, *paper, laser printing (each sheet)* and EQ198 *pacemaker follow-up system (incl software and hardware) (Paceart)* were both explained in the PE Summary of Recommendation (SOR) included with the RUC direct practice expense inputs recommendation for these services. The PE SOR explained that the paper is used to print reports to facilitate interpretation and the pacemaker follow-up system is used by the clinical staff. **The ACC urges CMS to accept the original RUC recommendation for CPT codes 93297 and 93298 and encourages CMS to reverse their proposal to create HCPCS code GTTT1 *Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*), to describe the services previously furnished under CPT code 93299.**

Myocardial Strain Imaging

The RUC appreciates CMS acceptance of the RUC recommended work RVUs and direct PE inputs for CPT Code 933X0. Regarding request for comment on 12 minutes of clinical labor time for clinical activity CA021, *perform procedure/service---NOT directly related to physician work time,* the ACC was confused by CMS's statement that "…no rationale was given for the RUC-recommended 12 minutes of clinical labor time for the activity CA021 "Perform procedure/service," and we are requesting comment on the appropriateness of this allocated time value." The use of clinical activity CA021 indicates that the clinical staff works independently of the physician to, in the case of this service, provide imaging. Granular detail regarding what the clinical staff completes during the intra-service (of service period) clinical activity, *perform procedure/service---NOT directly related to physician work time,* is provided in the PE SOR included with the direct practice expense inputs recommendation for these services. In recent years CMS has requested that any rationale for individual direct practice expense inputs be moved from the PE spreadsheet to the PE SOR. In the PE SOR for 933X0 there was explanation that the clinical activity CA021 performed by clinical staff type, L050A *Cardiac Sonographer* requires 12 minutes for the clinical staff to acquire the myocardial strain echocardiographic images. Additional detail regarding the activities that are typically performed by the cardiac sonographer for CPT code 933X0 are as follows:

> The sonographer will capture 2D cine loops from three standard apical images, adjusting the image for depth to include a portion of the left atrium and ensuring the LV is not foreshortened. A frame rate of > 50 fps is needed for resolution of the endocardium. The apical three chamber (Ap3C) cine loop is captured with the aortic valve adequately visualized. Aortic valve closure (AVC) time will be measured either by direct visualization of the valve or measured with spectral Doppler. The AVC time is necessary for calculation of peak systolic strain. (Depending on the echo machine, the AVC may be electronically calculated, but verification is needed by the

sonographer before accepting AVC time.) Utilizing the vendor's strain measurement package on the echo machine, automated tracking of the endocardium is visualized. Careful attention to the automated tracking of the endocardium is necessary and manual adjustments are performed by the sonographer as needed. This critical attention to detail is the most time-consuming portion of the procedure. The process is repeated for both the apical four chamber (Ap4C) and apical two chamber (Ap2C) 2D cine loops after again adjusting for depth, frame rate and resolution. After acquiring three separate apical strain images, an automated 'bulls-eye' view of the systolic strain pattern is revealed and the image is acquired for regional assessment of segmental strain values.

Chronic Care Remote Physiologic Monitoring Services

994X0

In considering the work RVUs for the new add-on CPT code 994X0, CMS first considered the value of its base code 99457. CMS previously valued the base code at 0.61 work RVUs. Given the value of the base code, CMS does not agree with the RUC recommended work RVU of 0.61 for the add-on code. CMS proposes a work RVU of 0.50 for the add-on code, which is the survey 25th percentile work RVU. CMS references CPT code 88381 for microdissection (work RVU = 0.53 and 20 minutes intra-service/total time) for support.

Work and time are the same for the first 20 minutes and each additional 20 minutes for this remote physiologic monitoring treatment. There is no pre-service or post-service work associated with the base code so there are no efficiencies that would be gained when entering the additional 20 minutes. If a patient requires more than the first 20 minutes of remote physiological monitoring treatment management, then this patient is part of a subgroup of patients that need more care and extra attention. These patients have fluctuating physiologic parameters. For example, if patients with pressure monitors data are completely consistent, then less work is required, but if there are great fluctuations as in code 994X0, the clinician will need to need to provide more work analyzing and addressing these differences with medication modifications or other adjustments. There are multiple services in which the base and add on code are valued the same.

It may be helpful to explain the workflow for these patients. It is not the case that a clinician is in a room with one patient for 20 minutes, thus billing 99457 for this patient, then on another occasion in a room with a different patient for 40 minutes, thus billing 99457 and 994X0 for that patient. Instead, these codes are for remote services that account for the clinician's time to monitor and manage patients over the course of a month. It would take several inflection nodes during that month for management and communication to reach the threshold for the first 20 minutes with a relatively stable patient, and several additional nodes to reach the threshold for the second 20 minutes with a less stable patient. The work of using interpreted data and medical decision-making to assess a patient's clinical stability and alter care management for these time-

based codes is similar in minutes 1-5 as it would be for minutes 36-40. Since the quantity of time is identical, the work RVU should be the same.

The work for 994X0 is also the same as 99490 for chronic care management services (work RVU = 0.61 and 23 minutes total time). The typical patient receiving 994X0 has a chronic disease, specifically, heart failure and has a chronic heart failure management device at home to prevent hospitalization. Thus, CPT code 994X0 is similar to the chronic care management code 99490. **The ACC urges CMS to accept a work RVU of 0.61 for CPT code 994X0.**

Payment for E/M Office Visit Services

The ACC appreciates CMS's proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. The policy changes for the E/M office visits would be effective for services starting January 1, 2021. The CPT coding changes will retain 5 levels of coding for established patients; reduce the number of levels to 4 for new patients (by deleting 99201); and revise the code definitions and guidelines. A new CPT code for extended office visit time will also be implemented. The changes also revise the times and medical decision-making definitions for the office visit codes. History and physical exams should continue to be performed as medically appropriate; however, these elements will no longer be a consideration for code level selection. Physicians can choose the E/M visit level based on either medical decision making or time. This new coding framework will relieve administrative burden and better describe office visits as they are performed today. **The ACC urges CMS to finalize the CPT codes, CPT guidelines and RUC recommendations as submitted. To address negative effects of redistribution, CMS should work with the medical community in urging Congress to implement positive updates to the Medicare conversion factor to offset appropriate increases to office visits.**

Proposed Add-On Code GPC1X

CMS proposes to implement a Medicare-specific add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition. CMS does not provide any specific assumptions regarding the projected utilization for this new add-on code, though it appears from Tables 111 and 115 that cardiologists are predicted to use the code.

The ACC appreciates CMS's intent to ensure that physicians are adequately paid for those patients that are outliers to the typical patient described in the valuation of office visits. However, the vignettes utilized in the survey often describe a patient that would have ongoing primary care services and/or have a single, serious, or complex chronic condition. For example, the vignette for 99215 is *Office visit for an established patient with a chronic illness in a severe exacerbation that poses a threat to life or bodily function or an acute illness/injury that poses a threat to life or bodily function.* Regardless of service performed, a surgical procedure or an office visit, physicians

should have a way to identify outlier patients where additional payment is warranted. However, the proposed code GPC1X *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)* is not well defined and could prove confusing to physicians and coding personnel, leading to inconsistent and even unintentionally inappropriate use of the code. **The ACC recommends that CMS postpose the implementation of this add-on code, allowing the CPT Editorial Panel to better define the service to meet its intended purpose.**

Systematic Adjustments to Other Stand-Alone Codes

CMS also seeks comments on whether it is necessary to make systematic adjustments to other services to maintain relativity between these services and E/M office visits, and whether it is necessary to make corresponding adjustments to E/M codes describing visits in other settings. The ACC does not believe that CMS should make systematic adjustments to services without additional review by the CPT Editorial Panel and the RUC.

Surveyed Physician Time

CMS requests comments on physician time, noting that the median total time is not the same as the sum of median times from the different service periods. **The ACC urges CMS to adopt the RUC recommended median total time for the office visits.** The median total time is the most accurate reflection of how long the service typically takes. Each respondent reported three different times: the time spent for the three days before the date of the visit, the time spent on the date of the visit, and the time spent for the seven days after the visit. These three times were summed, and a total time determined for each respondent. The median total time was determined by taking the median of these summed times. It was not determined by taking the sum of the medians for pre-date of service time, date of service time, and postdate of service time. The most accurate time to evaluate the work of E/M is the total time, not the time on the date of the visit.

Practice Expense Direct Inputs

The ACC appreciates the CMS proposal to adopt nearly all the RUC recommendations for direct practice expense inputs for the office visit services. CMS declined to accept the desktop computer, ED021*, computer, desktop, with monitor*, used in examination rooms as a direct medical expense. We disagree with this decision. **The computer is dedicated solely to each patient throughout the visit to collect history, share and discuss lab and test results, and document the visit. It is an essential tool in conducting today's office visits and CMS should recognize it as a direct medical equipment cost.**

While certain instances exist throughout practice expense where a computer is considered indirect, it is not atypical for a computer to be included as a direct PE input. Equipment items should not be categorized as indirect across the board, rather their direct/indirect status should be considered based on the work that the clinical staff is performing using that piece of equipment on a code-by-code basis. For office visits the work being performed using the computer is not administrative in nature, it is used to record, analyze and communicate to the physician about every element of data that the clinical staff collects from the individual patient for the individual service. Further, the PPI survey, which is used in determining CMS allocation for indirect practice expense, is based on data provided by physicians at a time when computers were not standard equipment across all office visit codes. If CMS finalizes their proposal to remove equipment item ED021 from the direct PE inputs for office visits and considers it indirect, the office visit services will not account for the cost of the computer as it will effectively be left out of the direct and indirect practice expense associated with these codes.

Office Visits Included in Surgical Global Payment/Maternity Care

Surgical specialties participated in the RUC survey and their data often indicated longer time and greater amounts of work, than primary care and other specialties. However, CMS proposes not to apply the office visit increases to the visits bundled into global surgery payment. **The ACC recommends that CMS reconsider this position.**

Instead, CMS should implement the RUC recommendation to increase the post-operative office visits and maternity care bundled visits to retain relativity within the RBRVS. This would align with precedents when adjustments were made during the first 5-year review, third 5-year review, and elimination of consultation codes in 2011. Failure to adjust bundled post-operative visits would disrupt relativity in the fee schedule and effectively create specialty payment differentials.

Updates to PLI Inputs

CMS contracted with the Actuarial Research Corporation and has provided their interim report as part of supporting documentation to the proposed rule. In the CY 2018 final rule CMS indicated that the Agency would not finalize its proposal to use the most recent data for the CY 2018 professional liability insurance relative value units (PLI RVUs). Cardiology had been proposed to be assigned only a non-surgical risk factor in the CY 2018 proposed rule due to gaps in data. The ACC appreciates the Agency's efforts to improve the data collection and methodology surrounding PLI RVUs. The interim report describes how the process has been modified to increase the potential for obtaining premiums for historically underrepresented specialties and to reflect current understanding of the marketplace. **The ACC supports CMS's proposal for cardiology (06) to have both a surgery factor and no surgery factor, as in prior years.**

For CY 2020, CMS uses a broader set of PLI filings, available online from the System for Electronic Rates & Forms Filing (SERFF) Filing Access Interface and largest market share insurers in each state, to obtain a more comprehensive data set. This expansion of

filing subtypes beyond those listed as "physician" and "surgeon" represents a welcome methodological change from the prior update, resulting in an expanded amount of premium data available for specialties that previously had insufficient data. There were some states (non-SERFF) that did not have expanded subtypes readily available and the RUC encourages CMS to request this from the state insurance departments in the future. The Agency was successful in acquiring national premium data for sixteen additional specialties that were formerly mapped entirely to another specialty. There is no longer mention of the arbitrary threshold that triggered the crosswalk methodology used by CMS in developing the PLI RVUs for specialties for which there was not premium data for at least 35 states. The ACC appreciates CMS attempts to improve the premium data collection process. However, areas of concern remain on which further improvements could be made.

CMS proposes to combine minor surgery and major surgery premiums to create the surgery service risk group, which it claims will yield a more representative surgical risk factor. In the previous PLI RVU update, only premiums for major surgery were used in developing the surgical risk factor. CMS considers surgical services with physician work values greater than 5.00 as 'major surgeries' for this analysis. The Agency recognizes that inclusion of premiums for 'minor surgery' policies as well as 'major surgery' policies from insurers that charge different premiums based on a physician's case mix has resulted in national premiums and risk factors which are lower for surgical specialties.

There are three methodological flaws in implementing this new policy. 1) The definition of "minor" vs. "major" surgery is arbitrary and has led to undervaluation of certain specialties and codes; 2) certain specialties and services are unfairly penalized as premium rates vary significantly within the specialty; and 3) the physician work RVU shares by service risk type appear to be in error and need further explanation and review.

Policy makers have attempted to define "minor" and "major" surgery for years without success. CMS has selected an arbitrary definition, assigning any CPT code in the 10000-69999 section of CPT with a work RVU below 5.00 is considered minor surgery. While this may appear to be a reasonable approach, there are exceptions that must be made. For example, some codes with a ZZZ global period and work RVUs lower than 5.00 are clearly a component of major surgery. An example familiar to cardiologists is catheterization transseptal puncture code 93462. This service has 3.73 work RVUs but is a service that requires significant skill and risk.

Within specialties, physicians may subspecialize and perform very different services from other physicians in the same specialty. CMS has recognized this for decades in computing PLI RVUs. For example, cardiology premium data for cardiologists that do not perform surgery/invasive procedures is collected and applied to services that are not surgical; while premium data for those that do perform surgery/invasive procedures are collected and applied to surgical codes. **The ACC recommends CMS not implement its definitions for minor and major surgery.**

Imputation Methodology

In instances where there are no data corresponding to a CMS specialty in the insurer's rate filing, CMS proposes to use total imputation to establish premiums as displayed in Table 8.C.2.

A shortcoming of this approach is a failure to recognize cardiac electrophysiology as a specialty with surgical risk. This is a relatively small specialty that may not clearly show in premium data. However, it would **not** make sense for services like pacemaker implantation that includes placing transvenous wires inside the heart or catheter ablations to treat cardiac arrhythmias inside the heart to receive a non-surgical PLI risk factor. Cardiac electrophysiology currently has separate service risk groups for surgery and no surgery and CMS should remedy this in the final rule. **The ACC recommends that cardiac electrophysiology (21) be mapped to both cardiology (surgery) and cardiology (no surgery) (06).**

Another incongruous outcome of the imputation approach is a proposal for advanced heart failure and transplant cardiology (C7) be assigned the same "ALL" surgical risk factor as cardiac surgery. This specialty better maps to cardiology-nonsurgical than to cardiology- surgical because it does not actually involve the transplant surgery itself but the medical care pre and post op. Some members do perform services that are interventional/invasive, but most of their work is not surgical. Table 8.B indicates that advanced heart failure and transplant cardiology's share of total "work RVUs–no surgery" is 92%. **Thus, the ACC recommends that advanced heart failure and transplant cardiology (C7) be mapped to both cardiology (surgery) and cardiology (no surgery) (06).**

<u>Care Management Services</u>

Principal Care Management (PCM)

CMS proposes to create two new codes for Principal Care Management (PCM) services, which would pay physicians for providing care management to patients with a single high-risk disease. The current CCM codes require patients to have two or more chronic conditions.

This proposal deserves serious consideration and discussion and is best reviewed by the CPT Editorial Panel. CMS proposes this time-based code at the same time as proposing an add-on code for many office visits for a similar patient. In addition, there may be other codes that describe the work performed for these patients, including the office visit codes, just revalued to include time spent three days prior and seven days following each office visit. It is important that the service be appropriately described without overlap with other services.

Intensive Cardiac Rehabilitation (ICR)

The Bipartisan Budget Act of 2018 included language directing CMS to add covered conditions for ICR consistent with those for cardiac rehabilitation (CR). The ACC worked with other stakeholders to secure updated coverage indications for CR to treat chronic heart failure patients through the national coverage determination process in 2013 and 2014. The ACC understands that CMS must implement this change in response to statute and does not object to updated regulations to apply coverage consistent with Congress's wishes in § 410.49(b). The ACC supports CMS's proposal to distinguish between CR and ICR as it does in newly proposed § 410.49(b)(viii) where it notes that NCDs modifying covered conditions would apply to both CR and ICR so long as clinical evidence supports coverage for CR and ICR. CR and ICR are different services provided to different patient populations and, importantly, different evidence bases. The outcomes from study of one therapy may not translate to the other.

Potentially Misvalued Services

Code G0166 (*External counterpulsation, per treatment session*) was nominated as potentially misvalued by the public. Separately, the ACC has previously shared concerns about recent changes to the payment for inputs to this service. The College developed updated direct practice input recommendations for consideration by the RUC at the October 2019 meeting. Those will be shared immediately after that meeting for potential inclusion yet this year in the CY 2020 final rule.

Physician Supervision of Physician Assistant (PA) Services

Since 1986 PA services have been required to be furnished under CMS's definition of "general supervision of a physician." This means that PA services must be furnished under a physician's overall direction, but the physician's presence is not required during the performance of PA services. Seeking to expand flexibility and efficiency in the system and align with evolving state law on the topic, CMS proposes that physician supervision standards of PAs "would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed."

Guided by its *Health Policy Statement on Cardiovascular Team-Based Care and the Role of Advanced Practice Providers,* the ACC has previously weighed in on related proposals that a distinction exists between the ability of advanced practice providers (APPs) like PAs to perform tasks autonomously and their ability to practice independently. The former is a well-established practice, while the latter is controversial. The ACC and its members have long supported and promulgated the use care teams that include APPs. The College stated in health policy statement that APP members of the cardiovascular care team "have the requisite education, training, and experience to allow them greater autonomy, thus extending a team's capabilities." The flexibility of this approach aligns with examples such as PAs leading teams that coordinate transitions of care, organizing

chronic anticoagulation clinics, or manage multiple chronic conditions. Consistent with the health policy statement, the College supports highly trained APPs who are part of a care team practicing autonomously within the scope and ability of their licensure. This is generally accomplished with collaborative practice between a collaborating physician and APPs on the care team. CMS's proposal to align physician supervision of PA services with other regulations on physician collaboration for nurse practitioners (NPs) and clinical nurse specialists (CNSs) to defer to state law appears consistent the collaborative approach ACC espouses.

Review and Verification of Medical Record Documentation

Building on prior adjustments to burdensome documentation requirements such as allowing teaching physicians to review and verify notes made by a student in a patient's medical record for E/M services rather than having to redocument, CMS makes additional proposals to provide flexibility to both physicians, PAs, and APRNs (regardless of whether they are acting in a teaching capacity). When these clinicians document in the medical record and are paid under the fee schedule for professional services, CMS proposes to establish a general principle that allows the physician, PA, or APRN who furnishes and bills for professional services to review and verify, rather than redocument, information included in the medical record by other physicians, residents, nurses, students, and members of the medical team. **The ACC supports this proposal and appreciates CMS continuing to look for steps that can be taken to streamline care, reduce documentation burden, and, in this instance, minimize "note bloat."**

Conclusion

CMS consideration of the comments in this letter is appreciated. The ACC looks forward to ongoing engagement with CMS to develop policies that support clinicians' ability to focus on delivering high-quality care to patients. The ACC acknowledges the tremendous thought and planning CMS is undertaking to improve the healthcare system. Should you or staff need additional information or have clarifying questions, please contact James Vavricek, Director for Regulatory Affairs, at jvavricek@acc.org.

Sincerely,

Richard Kovacs, MD, FACC
President

Attachments