

September 3, 2019

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

Submitted electronically via regulations.gov

**Re: File Code CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 14, 2019)**

Dear Ms. Verma:

Thank you for the opportunity to comment on the Notice of Proposed Rule Making (*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 Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 15,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research and practice.

The American College of Nuclear Medicine (ACNM) is a professional organization that directly represents the interests of nuclear medicine physicians before legislative and regulatory bodies, other medical organizations, the media and general public. Our goal is to assure a legislative, legal, regulatory and economic framework that encourages and makes practicable the safe, appropriate use of nuclear medicine procedures to improve the quality of health care service available to patients.

Both our organizations appreciate the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the MPFS.

We offer comments and recommendations on the following topics addressed in this CY 2020 Proposed Rule:

- Proposed Valuation of Specific Codes for CY 2020

- (50) SPECT-CT Procedures (CPT Codes 78800, 78801, 78802, 78803, 78804, 788X0, 788X1, 788X2, and 788X3)
- (51) Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35)
- Evaluation and Management (E/M) Office Visit Services
- Appropriate Use Criteria

**(50) SPECT-CT Procedures (CPT Codes 78800, 78801, 78802, 78803, 78804, 788X0, 788X1, 788X2, and 788X3)**

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
<b>78800</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar limited single area (eg, head, neck, chest pelvis), single day of imaging	<b>0.64</b>	<b>0.70</b>
<b>78801</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, 2 or more areas (eg, abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days	<b>0.73</b>	<b>0.79</b>
<b>78802</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, single day of imaging	<b>0.80</b>	<b>0.86</b>
<b>78803</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), single area (eg, head, neck, chest pelvis), single day of imaging	<b>1.09</b>	<b>1.20</b>
<b>78804</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, requiring 2 or more days of imaging	<b>1.01</b>	<b>1.07</b>
<b>788X0</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest or pelvis), single day of imaging	<b>1.49</b>	<b>1.60</b>

<b>Code</b>	<b>Long Descriptor</b>	<b>CMS Proposed work RVU</b>	<b>RUC Recommended work RVU</b>
<b>788X1</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days	<b>1.82</b>	<b>1.93</b>
<b>788X2</b>	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging	<b>2.12</b>	<b>2.23</b>
<b>788X3</b>	Radiopharmaceutical quantification measurement(s) single area	<b>0.47</b>	<b>0.51</b>

Our societies worked collaboratively with the RUC regarding providing comments on this section of the proposed rule, and we reiterate and echo the RUC recommendations as outlined in their August 30<sup>th</sup> letter and in “blue text” in this letter. We have also provided additional comments in black text to assist CMS with further details that may not be in the RUC letter.

At the September 2018 CPT Editorial Panel meeting, the Panel revised 5 codes, created 4 new codes and deleted 9 codes to better differentiate between planar radiopharmaceutical localization procedures and SPECT, SPECT-CT and multiple area or multiple day radiopharmaceutical localization/distribution procedures.

The RUC agreed that these services met the Committee’s compelling evidence criteria for being potentially misvalued based on a change in technique/change in technology. Similar to PET-CT, there have been changes in SPECT and SPECT-CT instrumentation, computer processing, and software since the early 2010’s that allow extraction of more clinically valuable information regarding tumor, infection, inflammation, and the distribution of a variety of radiotracers. These changes have enhanced the data acquisition, data processing, quality control, and image interpretation while also adding new variables for acquisition protocols and analysis and have resulted in a shift in the typical patient.

**78800**

For CPT code 78800, CMS disagrees with the RUC recommended work RVU of 0.70 and proposes a work RVU of 0.64 by using an invalid total time ratio methodology (RUC recommended time divided by current time). CMS’s longstanding position, “...we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear

decrease in the valuation of work RVUs...”, is reiterated 18 separate times in the CY 2020 *Proposed Rule*. The total time ratio methodology CMS used for the proposed value for 78800 violates that stated position and is, therefore, inappropriate. Furthermore, the Harvard study lumped all pre-service, intra-service and post-service time into a single time field for diagnostic imaging procedures, making the comparison of the Harvard study’s time to the RUC’s intra-service time not a like-to-like comparison. As stated above, the procedure has changed due to changes in technique and changes in technology relative to when this service was last reviewed almost 30 years ago.

**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.** CMS’s continued practice of referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations is not appropriate. The Harvard study employed much less rigor when determining physician time relative to the modern RUC/CMS process.

The RUC recommendation was based on the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with comparison to 2<sup>nd</sup> key reference code 78305 *Bone and/or joint imaging; multiple areas* (work RVU= 0.83, intra-service time of 10 minutes, total time of 20 minutes) and CPT code 93289 *Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional...* (work RVU= 0.75, intra-service time of 10 minutes, total time of 24 minutes). CMS’ proposed value is based on a flawed initial assumption, is developed by a mere calculation and is not supported by a direct crosswalk. CMS should rely on valid survey data supported by clinical expertise. **The RUC urges CMS to accept a work RVU of 0.70 for CPT code 78800.**

#### **78801**

For CPT Code 78801, CMS disagrees with the RUC recommended work RVU of 0.79 and proposes a work RVU of 0.73 by adding the increment between the RUC recommendations for 78800 and 78801 to the CMS proposed value for 78800. As this methodology also is based on a total time ratio from CMS’ proposed value for 78800, this proposal is inappropriate as described in detail above.

**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.** CMS’ continued practice of referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations is not appropriate. The Harvard study employed much less rigor when determining physician time relative to the modern RUC/CMS process.

The RUC recommendation was based on the current work RVU which is supported by the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with comparison to top key reference code *78305 Bone and/or joint imaging; multiple areas* (work RVU= 0.83, intra-service time of 10 minutes, total time of 20 minutes) and CPT code *78070 Parathyroid planar imaging (including subtraction, when performed)*; (work RVU= 0.80, intra-service time of 10 minutes, total time of 20 minutes). CMS' proposed value is based on a flawed initial assumption, is developed by a mere calculation and not supported by a direct crosswalk. CMS should rely on valid survey data supported by clinical expertise. **The RUC urges CMS to accept a work RVU of 0.79 for CPT code 78801.**

### **78802**

For CPT Code 78802, CMS disagrees with the RUC recommended work RVU of 0.86 and proposes a work RVU of 0.80 by adding the increment between the RUC recommendations for 78800 and 78802 to the CMS proposed value for 78800. As this methodology also is based on a total time ratio from CMS' proposed value for 78800, this proposal is inappropriate as described in detail above.

The RUC recommendation was based on the current work RVU which is supported by the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with comparison to top key reference code *78306 Bone and/or joint imaging; whole body* (work RVU= 0.86, intra-service time of 10 minutes, total time of 20 minutes) and CPT code *78598 Quantitative differential pulmonary perfusion and ventilation (eg, aerosol or gas), including imaging when performed* (work RVU= 0.85, intra-service time of 10 minutes, total time of 24 minutes). CMS' proposed value is based on a flawed initial assumption, is developed by a mere calculation and not supported by a direct crosswalk. CMS should rely on valid survey data supported by clinical expertise. **The RUC urges CMS to accept a work RVU of 0.86 for CPT code 78802.**

### **78803**

For CPT Code 78803, CMS disagrees with the RUC recommended work RVU of 1.20 and proposes a work RVU of 1.09, which is the current work value for this service. CMS stated that their rationale for rejecting the RUC recommendation was due to a comparison of the RUC recommended times to the existing Harvard time for this code. The Harvard study lumped all pre-service, intra-service and post-service time into a single time field for diagnostic imaging procedures, making the comparison of the Harvard study's time to the RUC's intra-service time not a like to like comparison. Regardless, the change in total time was only 1 minute. Furthermore, as stated above, the procedure has changed due to changes in technique and changes in technology relative to when this service was last reviewed almost 30 years ago.

**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.** CMS' continued practice of referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations is not appropriate. The Harvard study employed much less rigor when determining physician time relative to the modern RUC/ CMS process.

SPECT and SPECT-CT services, which involves three-dimensional imaging, are relatively more intense services to perform than planar imaging codes 78800-78802 which do not involve three-dimensional imaging, and therefore would be expected to have a higher IWPUTs. The IWPUT of CMS' proposed value of 0.0292 would put this service at an inappropriately low intensity.

The RUC recommendation was based on the current work RVU which is supported by the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with comparison to top key reference code 78071 *Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT)* (work RVU= 1.20, intra-service time of 15 minutes, total time of 25 minutes) and CPT code 95908 Nerve conduction studies; 3-4 studies (work RVU= 1.25, intra-service time of 22 minutes, total time of 42 minutes). CMS' proposed value is based on a flawed initial assumption. **The RUC urges CMS to accept a work RVU of 1.20 for CPT code 78803.**

#### **78804**

For CPT Code 78804, CMS disagrees with the RUC recommended work RVU of 1.07 and proposes a work RVU of 1.01 by adding the increment between the RUC recommendations for 78800 and 78804 to the CMS proposed value for 78800. As this methodology also is based on a total time ratio from CMS' proposed value for 78800, this proposal is inappropriate as described in detail above.

The RUC recommendation was based on the current work RVU which is supported by the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to 2<sup>nd</sup> key reference code 78582 *Pulmonary ventilation (eg, aerosol or gas) and perfusion imaging* (work RVU= 1.07, intra-service time of 12 minutes, total time of 27 minutes) and MPC code 70460 *Computed tomography, head or brain; with contrast material(s)* (work RVU= 1.13, intra-service time of 12 minutes, total time of 22 minutes). CMS' proposed value is based on a flawed initial assumption, is developed by a mere calculation and not supported by a direct crosswalk. CMS should rely on valid survey data supported by clinical expertise. **The RUC urges CMS to accept a work RVU of 1.07 for CPT code 78804.**

#### **788X0**

For CPT Code 788X0, CMS disagrees with the RUC recommended work RVU of 1.60 and proposes a work RVU of 1.49 by adding the increment between the RUC recommendations for 78803 and 788X0 to the CMS proposed value for 78803. As CMS' proposed valuation for 78803

was based on an inappropriate comparison between the total Harvard study time and only the intra-service time from the RUC recommendation, they method used to derive this alternate recommendation is extremely flawed. The Harvard study lumped all pre-service, intra-service and post-service time into a single time field for diagnostic imaging procedures, making the comparison of the Harvard study's time to the RUC's intra-service time not a like to like comparison. Regardless, the change in total time was only 1 minute.

The RUC recommendation was based on the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC supported its recommendation with favorable comparison to top key reference and MPC code 78072 *Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization* (work RVU= 1.60, intra-service time of 20 minutes, total time of 30 minutes) and MPC code 99304 *Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components...* (work RVU= 1.64, intra-service time of 23 minutes, total time of 43 minutes). CMS' proposed value is based on a flawed initial assumption. **The RUC urges CMS to accept a work RVU of 1.60 for CPT code 788X0.**

#### **788X1**

For CPT Code 788X1, CMS disagrees with the RUC recommended work RVU of 1.93 and proposes a work RVU of 1.82 by adding the increment between the RUC recommendations for 78803 and 788X1 to the CMS proposed value for 78803. As CMS' proposed valuation for 78803 was based on an inappropriate comparison between the total Harvard study time and only the intra-service time from the RUC recommendation, they method used to derive this alternate recommendation is extremely flawed. The Harvard study lumped all pre-service, intra-service and post-service time into a single time field for diagnostic imaging procedures, making the comparison of the Harvard study's time to the RUC's intra-service time not a like to like comparison. Regardless, the change in total time was only 1 minute.

The RUC recommendation was based on the median work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to top key reference code 78812 *Positron emission tomography (PET) imaging; skull base to mid-thigh* (work RVU= 1.93, intra-service time of 30 minutes, total time of 50 minutes) and CPT code 95957 *Digital analysis of electroencephalogram (EEG) (eg, for epileptic spike analysis)* (work RVU= 1.98, intra-service time of 50 minutes, total time of 55 minutes). CMS' proposed value is based on a flawed initial assumption. **The RUC urges CMS to accept a work RVU of 1.93 for CPT code 788X1.**

#### **788X2**

For CPT Code 788X2, CMS disagrees with the RUC recommended work RVU of 2.23 and proposes a work RVU of 2.12 by adding the increment between the RUC recommendations for 78803 and 788X2 to the CMS proposed value for 78803. As CMS' proposed valuation for 78803 was based on an inappropriate comparison between the total Harvard study time and only the

intra-service time from the RUC recommendation, the method used to derive this alternate recommendation is extremely flawed. The Harvard study lumped all pre-service, intra-service and post-service time into a single time field for diagnostic imaging procedures, making the comparison of the Harvard study's time to the RUC's intra-service time not a like to like comparison. Regardless, the change in total time was only 1 minute.

The RUC recommendation was based on the median work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to CPT code 95939 *Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs* (work RVU= 2.25, intra-service time of 30 minutes, total time of 60 minutes) and MPC Code 99310 *Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components...* (work RVU= 2.35, intra-service time of 35 minutes, total time of 70 minutes). CMS' proposed value is based on a flawed initial assumption. **The RUC urges CMS to accept a work RVU of 2.23 for CPT code 788X2.**

### 788X3

For CPT Code 788X0, CMS disagrees with the RUC recommended work RVU of 0.51 and proposes a work RVU of 0.47 by multiplying the RUC recommendation by the reduction CMS had applied to 788X3. Applying a percentage reduction to a RUC recommendation is inappropriate and not resourced based. The work of add-on code 788X3 is a separate tangential service where the physician interprets and reviews a processed quantitated dataset and quality control information. Although 788X3 is an add-on code for SPECT-CT, the work of the add-on code differs markedly from the work of supervising and interpreting the SPECT-CT images themselves. The physician not only reviews and interprets the dataset, they commonly will redraw and reprocess to ensure reproducibility as they compare to prior images or datasets as decisions are often discussed with referring physicians for improvement or decline of patients' area of interest status and therefore this is a very intense service as patient management will rely heavily on the quantitative comparisons.

The RUC recommendation was based on the 25<sup>th</sup> percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to CPT code 77002 *Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)* (work RVU= 0.54, intra-service time of 15 minutes, total time of 17 minutes) and to top key reference code 78496 *Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (List separately in addition to code for primary procedure)* (work RVU= 0.50, intra-service and total time of 19 minutes). CMS' proposed value is based on a flawed initial assumption, is developed by a mere calculation and not supported by a direct crosswalk. CMS should rely on valid survey data supported by clinical expertise. **The RUC urges CMS to accept a work RVU of 0.51 for CPT code 788X3.**

**Practice Expense**

CMS is proposing refinements to the RUC recommended direct PE inputs for the codes in this family. CMS accurately observed that no written rationale was included for CA016 *Prepare, set-up and start IV, initial positioning and monitoring of patient* to exceed the standard package. The additional minute above the standard 2 minutes is to account for the additional handling of the radiotracer. Handling of a radiotracer requires more supplies, and a heavy leaded syringe holder, not to mention the added care to not contaminate a room, a patient or any equipment. If one drop of a tracer were spilled, it could shut down a room or set into motion a State and Federal set of rules for clean-up. Therefore, CA016 has traditionally been accepted by the RUC for nuclear medicine at a minimum of 3 minutes as all nuclear medicine services would require administration of at least one radiotracer. There are additional PE refinements for these services. **For the society's comments on individual refinements of direct PE inputs please see the attached refinement table in an excel file attached.**

As noted in the RUC comments to CMS, for nuclear medicine services and specifically for **CA016** the RUC has previously accepted the minimum standard of 3 minutes for this services across all our nuclear medicine codes that are planar studies. The additional minute(s) above the standard PE 2 minutes is to account for the additional handling of the radiotracers or setting up the patient in the camera. Handling of a radiotracer requires more supplies, and a heavy leaded syringe holder, not to mention the added care to not contaminate a room, a patient or any equipment. Therefore, CA016 has traditionally been accepted by the RUC for nuclear medicine at a minimum of 3 minutes as all nuclear medicine services would require administration of at least one radiotracer. As with SM022 noted below, another factor in the total number of minutes for this service is if the patient is having any type of SPECT where the camera is going to rotate round them, this is what occurs with a SPECT or a SPECT-CT studies. There is more time necessary above the 2 or 3 minutes because the camera will move in and out as it rotates around the patient, more time for positioning and explaining this to the patient is necessary and why we need 5 minutes total for SPECT or SPECT-CT studies, additional for SPECT or SPECT-CT that occur over two days we ask for 7 minutes which the RUC approved and CMS should accept.

We urge CMS to accept the individual code by code RUC recommended times as noted in our table below and as provide by the AMA RUC PE worksheets:

<b>CPT Code</b>	<b>Short description</b>	<b>CMS Code</b>	<b>RUC rec. Time</b>	<b>CMS prop refinement Time</b>	<b>Society Comments/rationale</b>
<b>78800</b>	Rp LTID planar single area, single day	CA016 * for L049A	<b>3 min</b>	2 min	Typical 1 day imaging, injection on separate day
<b>78801</b>	Rp LTID planar two areas or one area two days	CA016 * for L049A	<b>3 min</b>	2 min	Typical 2 day imaging, injection 2 & 24 hrs sep day
<b>78802</b>	Rp LTID planar whole body	CA016 * for L049A	<b>3 min</b>	2 min	Typical 1 day imaging, injection on separate day
<b>78803</b>	Rp LTID single area SPECT	CA016 * for L049A	<b>5 min</b>	2 min	Typical 1 day imaging

<b>78804</b>	Rp LTID planar single area whole body on two separate days	CA016 * for L049A	3 min	2 min	Typical 2 day imaging
<b>788X0</b>	Rp LTID single area SPECT-CT	CA016 * for L049A	5 min	2 min	Typical 1 day imaging
<b>788X1</b>	Rp LTID two or more areas SPECT	CA016 * for L049A	7 min	2 min	Typical 1 day imaging
<b>788X2</b>	Rp LTID two or more areas SPECT-CT	CA016 * for L049A	7 min	2 min	Typical 2 days imaging, injection on separate day

Rp LTID = Localization of tumor, infection or general distribution of a radiopharmaceutical

\*CA016 = initial patient set up, includes IV and pt positioning, standard 2 minutes, NM standard is typically 3 minutes. Depends on number of injections and number of days in imaging.

L049A = NM technologist

CMS also proposes to reduce a necessary supply required for nuclear medicine procedures, specifically **SM022** used to clean the nuclear medicine equipment room and the room to receive and measure the radiotracers. If the imaging is typically over 2 days then we need 10 because we need 5 each day. Also, if we have two radiotracers then we use 10 not 5 of the wipes because some of the wipes are used on camera and the area where the patient is given the injection(s) and others are used for the place where you receive and then go back to draw up the radiotracers. Therefore, for nuclear medicine studies that are **over two days or have two radiotracers** involved we utilize 10 wipes not 5. This is evidenced in 78451 and 78452 and many other NM codes. If there is one tracer and only one day of imaging then our number of sanitizing wipes are 5. We urge CMS to update the proposed rule with the RUC recommended inputs for SM022.

Finally, for our last request to the refinements for this family to the CMS proposal, we are sending to CMS our member invoices for equipment **ER097** gamma camera system, single-dual head SPECT CT currently in CMS data base price \$532,350.48. In July of 2013 our societies sent CMS four invoices of various configurations and prices, at that time we stated the most typical camera configuration was a Dual Head SPECT-CT with CT being a T-6. An average and typical negotiated price then and remains today is \$750,000 for this piece of equipment. Therefore, the CMS price for ER097 is undervaluing the RVWs for these services. **We urge CMS to update this equipment input price with an accurate cost, so that the RVW are calculated appropriately for services that contain ER097.** If this piece of equipment is not updated by CMS, any SPECT-CT procedure technical RVWs will not be relative to other planar, SPECT, PET or PET-CT nuclear medicine services.

**(51) Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35)**

<b>Code</b>	<b>Long Descriptor</b>	<b>CMS Proposed work RVU</b>	<b>RUC Recommended work RVU</b>
<b>78459</b>	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study;	<b>1.25*</b>	<b>1.61</b>
<b>78X29</b>	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	<b>1.40*</b>	<b>1.76</b>
<b>78491</b>	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic)	<b>1.00</b>	<b>1.56</b>
<b>78X31</b>	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	<b>1.11</b>	<b>1.67</b>
<b>78492</b>	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)	<b>1.74*</b>	<b>1.80</b>
<b>78X32</b>	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	<b>1.84*</b>	<b>1.90</b>
<b>78X33</b>	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);	<b>1.71*</b>	<b>2.07</b>
<b>78X34</b>	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	<b>1.90*</b>	<b>2.26</b>
<b>78X35</b>	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography, rest and pharmacologic stress (List separately in addition to code for primary procedure)	<b>0.42</b>	<b>0.63</b>

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

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.

### **Multiple Proposed Values**

Commenting on the proposal for this family of services is difficult because there are various iterations of what CMS is proposing in different sections of this *Proposed Rule*. 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. We urge CMS to consider a careful re-review of the RUC recommended values, that are the product of two surveys and several pre-facilitation workgroups over several RUC meetings to achieve. We also urge CMS to 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. It is clear to the RUC that the work of this technology builds and the CMS values place some of the higher levels of PET in with planar work, which does not make sense clinically.

**For six of the nine codes in this family there are different work RVUs indicated in the text of the *Proposed Rule*, Table 20: Proposed CY 2020 Work RVUs for New, Revised and Potentially Mis valued Codes and Addendum B.**

### **Change in Physician Work**

CMS is proposing to decrease the work RVUs for all the Myocardial PET codes. **CMS is ignoring the fact that the physician work has changed for these services.** Myocardial PET imaging has evolved in the past two decades. There have been changes in instrumentation, computer processing, and software since the mid 1990's that 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.

CMS is also disregarding prior relative nuclear medicine services that CMS approved survey values such as CPT code 78453 *Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)* (work RVU =1.00) and 78454 *Myocardial perfusion imaging, planar (including qualitative or*

*quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection (work RVU = 1.34). CMS is also disregarding or was not aware of the discussion by the several pre-facilitation committees regarding the prior times being less reliable due to the year of the prior survey and the lower number of survey respondents and lower number of available sites performing PET during that time period.*

### **Total Time Ratio**

**The invalid methodology of a total time ratio used 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.** The RUC would like to remind CMS of 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. The RUC is increasingly concerned that CMS is eschewing the bedrock principles of valuation within the RBRVS (namely, magnitude estimation, survey data and clinical expertise) in favor of arbitrary mathematical formulas.

### **Valuing the Increment**

The RUC is perplexed that CMS is only relying 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 cross walked to any service. CMS is using *78491 Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic)* 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. **The RUC 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 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 25<sup>th</sup> percentile for CPT code 78459. CMS is overlooking the change in physician work and that this service is different and stating that because of the reduction in time the recommended value is overestimated. CMS is proposing 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. The RUC address that 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 25<sup>th</sup> percentile work RVU of 1.61 appropriately accounts for the work required to perform CPT code 78459. This is a PET scan instead of examining at blood flow, as with the perfusion PET, it examines metabolism using a tracer, such as glucose. The RUC agreed that CPT code 78459 requires slightly more physician work than code 78491 *Myocardial imaging PET perfusion, single study* (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 78452 *Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection* (work RVU = 1.62 and total time of 40 minutes) and 78811 *Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)* (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 74176 *Computed tomography, abdomen and pelvis; without contrast material* (work RVU = 1.74 and total time of 32 minutes). **The RUC 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 25<sup>th</sup> percentile for CPT code 78X29. CMS is proposing 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. The RUC address that 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 25<sup>th</sup> 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 *Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional* (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 *Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)* (work RVU = 1.78 and total time of 32 minutes). **The RUC 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 25<sup>th</sup> percentile. CMS is ignoring the change in physician work and that this service is different and stating that because of the reduction in time the recommended value is overestimated. CMS is proposing 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 *Acute gastrointestinal blood loss imaging* (work RVU = 0.99) and CPT code 10021 *Fine needle aspiration biopsy, without imaging guidance; first lesion* (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, which CMS bases their proposed values.** A work RVU of 1.00 vastly underestimates the physician work required to perform this service. The survey 25<sup>th</sup> 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 *Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection* (work RVU = 1.62 and total time of 40 minutes) and 78811 *Positron emission*

*tomography (PET) imaging; limited area (eg, chest, head/neck)* (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 *Computed tomography, abdomen and pelvis; without contrast material* (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 we noted earlier CMS is comparing 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. The CPT 78278 is clearly less work than 78491 as well as several other of the new cardiac PET codes. CMS should review the CPT code 78453 *Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)* (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 3D CT study and would create a clear to the medical community rank order problem 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 RUC 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 is proposing a work RVU of 1.11 by applying the RUC recommended increment 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 *Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional)* (work RVU = 0.97) and CPT code 93284 *Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system* (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. The RUC address that in the preliminary comments for this family of services. Additionally, CMS's statement that valuing CPT code at the survey 25<sup>th</sup> 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 25<sup>th</sup> 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 *Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)* (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 *Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization* (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 *Insertion of a temporary prostatic urethral stent, including urethral measurement* (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 a neurostimulator and the other a cardiac device, however, but both are monitors that are reviewed. 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 5-20-5/30 (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 RUC 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 25<sup>th</sup> percentile for CPT code 78492. CMS states that they are proposing 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. The RUC address that 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 25<sup>th</sup> 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 Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection* (work RVU = 1.62 and total time of 40 minutes) and *78812 Positron emission tomography (PET) imaging; 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 Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional* (work RVU = 1.75 and total time of 40 minutes) and similar service code *70552 Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)* (work RVU = 1.78 and total time of 32 minutes). **The RUC 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 Chemo denervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed* (work RVU = 1.90), since the survey 25<sup>th</sup> 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 is proposing 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. The RUC address that in the preliminary comments for this family of services.

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 *Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)* (work RVU = 2.40 and total time of 50 minutes) and 78814 *Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)* (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 *Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 7.6 cm to 12.5 cm* (work RVU = 1.98 and total time of 37 minutes). **The RUC 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 25<sup>th</sup> 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 proposing 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. The RUC address that in the preliminary comments for this family of services.

A work RVU of 1.71 underestimates the physician work required to perform this service. The survey 25<sup>th</sup> 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 Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)* (work RVU = 2.40 and total time of 50 minutes) and *78815 Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; 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 Colposcopy of the vulva; with biopsy(s)* (work RVU = 12.05 and total time of 45 minutes). **The RUC 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 Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences* (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 is proposing 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. The RUC address that in the preliminary comments for this family of services.

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 *Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences*; (work RVU = 2.60 and total time of 65 minutes) and 78815 *Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; 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 RUC 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**

CMS disagrees with the RUC recommended work RVU of 0.63 for CPT code 78X35 based on the survey 25<sup>th</sup> percentile. CMS states they believe 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 *Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)* (work RVU = 0.33) and 11105 *Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)* (work RVU = 0.45).

Proposing a 1/3 reduction because that is 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 25<sup>th</sup> 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. There are a variety of regions of interest to review and a variety of curves to match 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 *Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (List separately in addition to code for primary procedure)* (work RVU = 0.50 and intra-service/total time of 19 minutes) and 93567 *Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supraaortic aortography (List separately in addition to code for primary procedure)* (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 25<sup>th</sup> 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 *Voiding pressure studies, intra-abdominal (ie, rectal, gastric, intraperitoneal) (List separately in addition to code for primary procedure)* (work RVU = 0.80 and total time of 15 minutes) and 96411 *Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)* (work RVU = 0.20 and total time of 7 minutes). **The RUC 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.**

### **Practice Expense**

CMS is proposing 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 on 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 unreasonable for CMS to propose that the software should be removed. Historically, all 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 you cannot run it. **The RUC 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 RUC will submit separate invoices for the software and the hardware if they become available. Please also find an additional invoices for new equipment item ER110, PET Refurbished Imaging Cardiac Configuration included as an attachment.** *(Attachment 05 in the RUC recommendations)*

CMS is also proposing a 90% utilization rate for both PET and PET/CT equipment. CMS has not based this decision on any data nor asked the specialty societies if any information was available. As a point of information, the FDA does require 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 Rb 82 from each of their generators. (NOTE: The great majority of facilities use just one generator at a time.) These data, which have been collected for over seven years, show an overall average of 4.5 patients imaged per facility per day. CMS should receive more specific information from manufacturers and providers, however the RUC can share our medical specialty expertise in that hospitals can perform cardiac PET or PET-CT and oncology PET or PET-CT procedures with the same or similar resources (shared PET or PET-CT equipment and personnel). However, 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 and IDTF setting confirm that a 50% utilization would be a more accurate utilization that is based on data and not CMS inaccurate assumption. **The RUC urges CMS to use the 50% utilization rate on both the PET and PET-CT equipment.**

### **Contractor Pricing**

Historically, for nuclear medicine PET services CPT 78459, 78491 and 78492, CMS has set professional relative values and left the technical component to the local contractors as “C” Contractor-priced (aka carrier priced) codes. In the proposed CY 2020, CMS is proposing to generally accept the RUC technical inputs and invoices to set the technical and global rates. Our societies do support the process of moving from carrier priced code to establishing relative values based on RUC and stakeholder invoices and inputs. However, we are deeply concerned that CMS did not accept all the RUC inputs and assumptions resulting in a technical RVW that does not represent the costs of these services. **To that end, there are updated invoices for ER110 and New Equipment NO CMS number in proposed rule, Quantitative Blood Flow Reserve that should be used by CMS, and updated inputs that CMS can make in the CY 2020 final rule as noted in the attached excel file, along with phasing in this family over time. Finally, CMS should consider utilizing the most recent contractor priced claims data (2018) for paid claims for CPT 78459, 78491 and 78492 (utilizing a weighted average) in the physician office and IDTF setting that would stabilize a payment for CY 2020 giving the community time to review a finalized RVW with updated inputs for use in CY 2021.**

CMS has proposed a technical rate of \$272, with a \$349 global rate for CPT 78492 in CY 2020. If we compare the \$272, and \$349 respectively to the 2017 actual weighted average paid claims rate of \$1,145 (discussed later in this letter) that could result in a 72% reduction. One can easily see that without corrections to the inputs following the RUC and stakeholder provider input AND, accepting updated equipment utilization rates, updated invoices AND phasing in, CMS could put this import technology in jeopardy.

### **Equipment Utilization Rate**

Our members have provided additional PET invoices to the already supplied RUC invoices from the RUC meeting for ER110 which CMS must use to set the updated camera price (see table 1 at the end of this letter). As noted by the RUC one very important element in the formula is that CMS must use the 50% utilization in the calculation for these services, as not doing this will significantly under value the service for the physician office and IDTF setting of care.

Additionally, our societies have provided data (see Table 2 at the end of this letter) to support a 50% utilization, over a 90% utilization. These FDA required data, which have been collected for over seven (7) years, show an overall average of 4.5 patients imaged per facility per day. We encourage CMS not to mix up hospital utilization with the office setting utilization. Table 2 even with showing both hospital and MPFS setting data together, clearly support the 50% utilization.

These PET services existed in 2010 when CMS made the decision to apply the 90% utilization rate only to CT and MRI services. Since then nothing has changed. CMS stated, *“As indicated above, we are not finalizing our proposal to increase the utilization rate assumption for expensive equipment other than MRIs and CTs, including therapeutic equipment.”* We are not aware of any statutory requirement to assume a 90% utilization for PET imaging (with or without CT. From ATRA, [PUBLIC LAW 112-240—JAN. 2, 2013 Sec. 635 Section 1848 of the Social Security Act \(42 U.S.C. 1395w-4\)](#) is amended—in subsection (b)(4)(C)—(A) by striking “and subsequent years” and inserting “, 2012, and 2013”; and (B) by adding at the end the following new sentence: “With respect to fee schedules established for 2014 and subsequent years, in such methodology, the Secretary shall use a 90 percent utilization rate.”; and (2) in subsection (c)(2)(B)(v)(III), by striking “change in the utilization rate applicable to 2011, as described in” and inserting “changes in the utilization rate applicable to 2011 and 2014, as described in the first and second sentence, respectively, of”. The requirement as we understand it, is only to assume 90% utilization for specific services (and CPT codes) identified in the CY 2010 final rule, therefore, CT and MRI. We are not aware that the list from CY 2010 has been updated. We have provided data as will other companies in our industry, yet CMS has only made the decision based on an incomplete assumption. CMS mentions in the CY 2010 that data is necessary to make these decisions, we agree with CMS. Additionally, our invoices have shown the cost of a PET alone is not close to the 1 Million dollar figure referenced.

Of importance, a PET-CT is ordered because a PET scan is needed, not a CT. The CT is secondary and supplemental to the PET imaging. Also, CPT makes clear in parentheses, if a diagnostic CT is needed, the CT is ordered separately with different protocol and separate report. Providers will append the modifier 59 as directed by CPT for that separate full diagnostic CT. CMS did not provide any data in this proposed rule to support a 90% utilization rate. If we subtract the costs of the CT from the PET the equipment would not reach 1 Million dollars even for a PET-CT. We believe that PET with out CT clearly does not meet the monetary criteria. For PET-CT we equally urge CMS to consider the data and assign a 50% utilization rate. **We urge CMS to use the 50% utilization for all nuclear medicine equipment and specifically for new equipment ER110 and ER111.**

### **Transition**

We are also concerned regarding a rapid transition from contractor priced to relative values that are significantly lower than current rates and will negatively impact patient access and provider disruptions in services. Shifting is likely to occur moving these procedures to the hospital setting where the technical rate is closer to the hospital national technical rate. We believe that CMS should use the most current paid (2018) contractor claims for CPT 78459, 78491 and 78492, for establishing a weighted average technical rate (this can be converted to RVWs) to understand the impact for each CPT code (78459, 78491 and 78492) and for these services. CMS could consider using that weighted average for CY 2020 while the community has an opportunity to see CMSs updated RVWs for future years. We urge CMS to use its authority to phase this change in so as not to disrupt services. As per the intent of PAMA, no procedure should be reduced by more than 20% in any one year or CMS should phase it in. While PAMA can be argued if it applies or not to CPT 78459, 78491 and 78492, we believe CMS should consider that it **DOES apply** especially for the intent, since the services have been provided for many prior years. **We urge CMS to phase in any PET or PET-CT service in the CY 2021 to no more than a 20% reduction for the technical or global in any one year, so as to not jeopardize the access for patients and any recent purchases by this community.**

As an example of a weighted average, we researched the 2017 publicly available claims data for CPT 78492 the highest volume cardiac PET study today. We removed the paid Non facility claims that were less than \$300 as those can be assumed to be the professional rates. We then took the weighted average of the rest of the paid claims and came up with a final weighted average of \$1145 dollars for CPT 78492. This \$1,145 rate could be for either technical only or global since the public data does not supply that level of detail to sort out the two. We know that CMS has access to more accurate methods and more current data to calculate both the technical and the global weighted average paid rates, such that they would be able to provide for the final rule for CY 2020 an accurate rate and converted relative value for a final rate for CY 2020. For CY 2021, if those rates would be reduced less than 20% we urge CMS to phase them in, consistent with PAMA.

### **Practice Expense**

#### **Supply**

As with the SPECT and SPECT-CT family in item 50 of the Proposed rule, CMS also proposes to reduce a necessary supply required for these nuclear medicine procedures, specifically **SM022** used to clean the nuclear medicine equipment room and the room to receive and measure the radiotracers for the PET and PET-CT services. **We urge CMS to update the proposed rule with the RUC recommended inputs for SM022.**

### **Invoice Submission**

CMS routinely accepts public submission of invoices as part of the process for developing payment rates for new, revised, and potentially mis valued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2020, CMS

noted that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, CMS generally needs to receive invoices by the same February 10th deadline noted for consideration of RUC recommendations. However, CMS would consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

The SNMMI and ACNM are supportive of CMS being able to accept additional invoices for equipment from our members through either the RUC submission or through a process for our members to submit directly to CMS. Our members have informed us that providing invoices is often challenging due to the contractual arrangements they have with vendors and not disclosing final invoice costs. Therefore, providing invoices via an open comment period is challenging for our members since all submitted comments are public. We would appreciate CMS outlining an alternate method to maintain confidential submission directly to CMS outside of the open comment process so that our members can submit directly to CMS. **We will greatly appreciate CMS willingness to accept additional invoices for setting accurate pricing of all equipment necessary for the new family of CPT codes.**

#### **Evaluation and Management (E/M) Office Visit Services**

SNMMI and ACNM appreciates the CMS proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. **We urge the Agency to finalize your acceptance of the CPT codes, CPT guidelines and RUC recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC. CMS should work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the deserved increases to office visits.**

#### **Appropriate Use Criteria (AUC)**

CMS was silent in the proposed CY 2020 rule regarding implementation of this significant added burden to the medical community that is scheduled to begin on January 1, 2020. We urge CMS to provide notice, education and implementation guidance in the final rule so that providers are prepared to supply the information to nuclear medicine providers that will be necessary to comply with the sub regulatory information in CR 11268. We are working with qualified decision support mechanisms for the proper implementation of these criteria. However, CMS has developed HCPCS modifiers along with HCPCS CPT codes that will require referring physician provider education to implement properly. We are concerned that CMS has not done enough education to the referring physician community. While our societies will provide education to our members, we believe that CMS should take a lead role in provider education to the referring physicians.

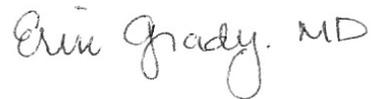
## Conclusion

SNMMI and ACNM appreciates the opportunity to comment on the MPFS CY 2020 Proposed Rule to the CMS. As always, we are ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Sukhjeet Ahuja, Senior Director of Health Policy and Quality at sahuja@snmmi.org or (703) 326-1195.

Respectfully Submitted,



Vasken Dilsizian, MD  
President, SNMMI



Erin Grady, MD, FACNM  
President, ACNM

**Table 1** Summary of Additional Invoices

Numb ID	CMS Equipment Number	Name of Equipment	Total Invoice Price	Company	Year	Comment
#1	ER110	PET Camera	\$465,000.00	Positron	2017	
#2	ER110	Refurbished PET system	\$522,156.25	Nuclear Imaging Services	2018	
#3	ER110	Refurbished Siemens LSO PET System	\$555,000.00	Nuclear Imaging Services	2017	
#4 #1	ER110 And ERXXX	Refurbished Siemens LSO PET System  Quantitative Blood Flow Software & Hardware	\$600,000.00 <i>minus \$50,000. Cost of quantitative blood flow hardware and software</i> <b>Total 550,000.00</b>	Nuclear Imaging Services	2016	This invoices contained an invoice for the 4DM quantitative software and hardware package therefore listed both equipment numbers.
#5 #2	ER110 And ERXXX	Refurbished Siemens PET Scintron  Quantitative Blood Flow Software & Hardware	\$562,000.00 <i>minus \$50,000. Cost of quantitative blood flow hardware and software</i> <b>Total 512,000.00</b>	Nuclear Imaging Services	2018	This invoices contained an invoice for the 4DM quantitative software and hardware package therefore listed both equipment numbers.
#1	ER111	PET-CT cardiac package	1,460, 621.00			
#6	ER110	Refurbished Siemens PET	\$517,500.00	Nuclear Imaging Services	2016	
#7	ER110	Refurbished Siemens/CTI PET	\$500,000.00	Nuclear Imaging Services	2017	
#3	No CMS code yet ERXXX	New Cardiac Quant Software and Hardware	\$47,053.44	General Electric	2010	
#4	No CMS code yet ERXXX	New Cardiac Quant Software and Hardware	\$39,740.56	Siemens	2017	

**Hard copies of invoices in summary Table 1 sent to CMS via federal express.**

**Table 2** Supplied by Bracco Diagnostics one of two manufacturers of Rubidium-82 used for cardiac PET perfusion imaging.

Bracco is required by the FDA to collect and submit use data from the facilities utilizing CardioGen-82 generators for Cardiac PET imaging. One of the data points collected each day from each facility is the number of patients imaged with Rb 82 from each of their generators. (NOTE: The great majority of facilities use just one generator at a time.) These data, which have been collected for over seven (7) years, show an overall average of 4.5 patients imaged per facility per day<sup>1</sup>.

Table 2. Bracco Diagnostics CGEN-106 study data 2012-2019YTD

Summary on total number of patients/day per site					
year	maximum	median	mean	25% q1	minimum
2012	11.6	4.0	4.3	2.4	0.4
2013	9.8	3.7	4.0	2.4	0.5
2014	11.2	3.8	4.1	2.4	0.9
2015	12.1	4.0	4.3	2.6	0.3
2016	13.0	4.2	4.5	2.6	0.6
2017	15.6	4.8	4.9	3.1	0.7
2018	17.1	4.9	5.0	3.2	0.5
2019	17.4	5.0	5.1	3.3	0.9