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September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1676–P
P.O. Box 8016
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

The Society for Vascular Surgery (SVS), a professional medical society composed of 5,800 specialty-trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease, offers the following comments on the Centers for Medicare and Medicaid Services' (CMS) Calendar Year (CY) 2018 Medicare Physician Fee Schedule (MPFS) Proposed Rule.

Endovascular Repair Procedures (CPT codes 34X01, 34X02, 34X03, 34X04, 34X05, 34X06, 34X07, 34X08, 34X09, 34X10, 34X11, 34X12, 34X13, 34812, 34X15, 34820, 34833, 34834, 34X19, and 34X20)

The SVS would like to thank CMS for proposing to accept the Relative Value Scale Update Committee (RUC)-recommended work Relative Value Units (RVUs) for all 20 codes in this family. We believe that the RUC-recommended work RVUs are correct for all 20 codes.

Codes 34X01-34X08

Prior to the endovascular aneurysm repair (EVAR) coding changes, EVARs performed for rupture and in elective circumstances were reported with the same code. This is an historical artifact because the original codes were developed exclusively for elective repair. In 2000, it was not technically feasible to repair a ruptured aortic aneurysm using endovascular techniques. Over time, physicians developed the appropriate skill such that endovascular repair of a ruptured aortic aneurysm is now possible.

In general, the elective endovascular repairs (34X01, 34X03, 34X05, 34X07) represent approximately 85 percent of reported services, while the repair of ruptured aneurysms (34X02, 34X04, 34X06, 34X08) represent approximately 15 percent of total reported services. For the much more common elective repairs, the RUC-recommended work RVUs are significantly lower than current value of the component services that were bundled. For the less common ruptured aneurysm repair, the RUC-recommended

work RVUs are higher than the existing value of the component services that were bundled; however, the entire package results are a net reduction in work RVUs, despite the fact that the additional work associated with ruptured aortic and iliac aneurysms was never considered when this family of endovascular repairs was created.

CPT Code 34X01

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 23.71 for CPT code 34X01.

This new code bundles pre-service endograft planning, bilateral non-selective catheterization, endograft deployment, all angioplasty and/or stenting and all proximal and/or distal extensions from the level of the renal arteries down to the level of the aortic bifurcation, and all radiologic S&I.

We appreciate that CMS recognizes that a work RVU of 23.71 is the correct relative value for 34X01 within this family of EVAR codes and relative to other codes in the MPFS.

CPT Code 34X02

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 36.00 for CPT code 34X02. However, CMS requests comment on an alternative work RVU of 32.00 based on the survey 25th percentile and relative to CPT code 48000 (Placement of drains, peripancreatic, for acute pancreatitis), which has the same intraservice time of 120 minutes and a work RVU of 31.95. CMS indicates that the agency was unable to find any 90-day global services with 120 minutes of intraservice time and approximately 677 minutes of total time that had a work RVU greater than 36.00.

Code 48000 is not a valid comparator code for several reasons. First, the code did not undergo a full RUC survey; second, the code has an extremely low utilization; and third, a mini-survey was conducted that resulted in a specialty work RVU recommendation of 39.49. However, the RUC determined not to accept mini-survey results and instead applied a work RVU percentage adjustment based on a full survey of code 48005, which was deleted in 2007.

A ruptured aortic aneurysm is a catastrophic event. These patients present in varying degrees of hemorrhagic shock and without rapid treatment, death is certain. Patients are critically ill post-procedure, typically plagued by multisystem organ failure and despite high quality post-operative care, a portion of them still die. Despite advances in detection and treatment of aneurysmal disease, the rupture rate has remained relatively constant over the past two decades at roughly 15 percent of the total number of patients who present for abdominal aortic and iliac aneurysm repair. Code 34X02 offers a less invasive approach for treatment, but remains an extremely intense service in an attempt to save the life of an actively dying patient. Code 34X02 captures significantly different work compared to an elective aneurysm repair and includes the additional work of temporary balloon aortic occlusion as needed for hemodynamic instability as well as the significantly different, longer and more complex post-operative care.

We acknowledge that identifying comparator codes may be difficult if the focus is only on the survey code intraoperative and total time. Procedures which have high intensity and/or procedures with low intraoperative time, but high pre- and post-operative work are difficult to compare using these parameters. In this instance, it is more logical to consider intraoperative intensity to find comparator codes as support that the RUC-recommended work RVU is correct.

The table below was presented to the RUC to demonstrate that the median work RVU of 36.00 results in an intraoperative work intensity of 0.1369 that is relative to other highly intense services. This type of analysis allows for comparison of intraoperative work relativity across codes that have variable pre- and post-operative work.

We believe the discussion at the RUC about the inherent intense nature of 34X02 and appropriate relativity to other similarly intense procedures supports the RUC-recommended work RVU of 36.00.

СРТ	Descriptor	IWPUT	RVW	INTRA	Total Time
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	0.1335	29.40	150	457
47130	Hepatectomy, resection of liver; total right lobectomy	0.1338	57.19	240	870
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	0.1345	33.36	180	477
33681	Closure of single ventricular septal defect, with or without patch;	0.1369	32.34	150	507
34X02	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture, including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)	0.1369	36.00	120	677
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion	0.1372	19.85	120	225
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	0.1386	24.05	120	367
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	0.1403	25.00	120	395
43313	Esophagoplasty for congenital defect (plastic repair or reconstruction), thoracic approach; without repair of congenital tracheoesophageal fistula	0.1741	48.45	178	713
45126	Pelvic exenteration for colorectal malignancy, with proctectomy (with or without colostomy), with removal of bladder and ureteral transplantations, and/or hysterectomy, or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), or any combination thereof	0.1983	49.10	120	755

CPT Code 34X03

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 26.52 for CPT code 34X03.

This new code bundles pre-service endograft planning, bilateral non-selective catheterization, endograft deployment, all angioplasty and/or stenting and all proximal and/or distal extensions from the level of the renal arteries down to the level of the aortic bifurcation, and all radiologic S&I.

We appreciate that CMS recognizes that a work RVU of 26.52 is the correct relative value for 34X03 within this family of EVAR codes and relative to other codes in the MPFS.

CPT Code 34X04

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 45.00 for CPT code 34X04. However, CMS requests comment on an alternative work RVU of 40.00 based on the survey 25th percentile and relative to code 33534 (Coronary artery bypass, using arterial graft(s); 2 coronary arterial grafts), which has a work RVU of 39.88. The agency notes that code 33534 has 193 minutes of intraservice time, but a lower total time of 717 minutes. CMS indicates it was unable to find any 90-day global services with 180 minutes of intraservice time and approximately 737 minutes of total time that had a work RVU greater than 45.00.

Code 33534 is not a valid comparator code for several reasons. First, the value for code 33534 is not based on a RUC survey using magnitude estimation, but rather a calculation using a building block methodology based on the STS adult cardiac database using the mean intraoperative time and mean length of stay. In addition, the intensity used for calculation was surveyed separately and the pre- and post-service time and visits were developed by an expert panel. More importantly, the typical patient undergoing a two graft CABG is not typically urgent or emergent, but rather scheduled. In comparison, a ruptured aortic aneurysm is a catastrophic event. These patients present in varying degrees of hemorrhagic shock and without rapid treatment, death is certain. Patients are critically ill post-procedure, typically plagued by multisystem organ failure and despite high quality post-operative care, a portion of them still die. Despite advances in detection and treatment of aneurysmal disease, the rupture rate has remained relatively constant over the past two decades at roughly 15 percent of the total number of patients who present for abdominal aortic and iliac aneurysm repair.

Code 34X04 offers a less invasive approach for treatment, but remains an extremely intense service in an attempt to save the life of an actively dying patient. Code 34X04 captures significantly different work compared to an elective aneurysm repair and includes the additional work of temporary balloon aortic occlusion as needed for hemodynamic instability as well as the significantly different, longer and more complex post-operative care.

We acknowledge that identifying comparator codes may be difficult if the focus is only on the survey code intraoperative and total time. Procedures which have high intensity and/or procedures with low intraoperative time, but high pre- and post-operative work are difficult to compare using these parameters. In this instance, it is more logical to consider intraoperative intensity to find comparator codes as support that the recommended work RVU is correct.

The table below was presented to the RUC to demonstrate that the median work RVU of 45.00 results in an intraoperative work intensity of 0.1413 that is relative to other highly intense services. This type of analysis allows for comparison of intraoperative work relativity across codes that have variable pre- and post-operative work.

We believe the discussion at the RUC about the inherent intense nature of 34X04 and appropriate relativity to other similarly intense procedures supports the RUC-recommended work RVU of 45.00.

СРТ	Descriptor	IWPUT	RVW	INTRA	Total Time
47130	Hepatectomy, resection of liver; total right lobectomy	0.1338	57.19	240	870
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	0.1345	33.36	180	477
33681	Closure of single ventricular septal defect, with or without patch;	0.1369	32.34	150	507

СРТ	Descriptor	IWPUT	RVW	INTRA	Total Time
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion	0.1372	19.85	120	225
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	0.1386	24.05	120	367
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	0.1403	25.00	120	395
34X04	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uniiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture, including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)	0.1413	45.00	180	737
43313	Esophagoplasty for congenital defect (plastic repair or reconstruction), thoracic approach; without repair of congenital tracheoesophageal fistula	0.1741	48.45	178	713
45126	Pelvic exenteration for colorectal malignancy, with proctectomy (with or without colostomy), with removal of bladder and ureteral transplantations, and/or hysterectomy, or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), or any combination thereof	0.1983	49.10	120	755

CPT Code 34X05

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 29.58 for CPT code 34X05.

This new code bundles pre-service endograft planning, bilateral non-selective catheterization, endograft deployment, all angioplasty and/or stenting and all proximal and/or distal extensions from the level of the renal arteries down to the level of the aortic bifurcation, and all radiologic S&I.

We appreciate that CMS recognizes that a work RVU of 29.58 is the correct relative value for 34X05 within this family of EVAR codes and relative to other codes in the MPFS.

CPT Code 34X06

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 45.00 for CPT code 34X06. However, CMS requests comment on an alternative work RVU of 40.00 based on the survey 25th percentile and a comparison to CPT code 34X04, with two fewer minutes of intraservice time and total time. CMS also indicates it believes the survey respondents thought that these two codes had a comparable amount of work, as the survey 25th percentile work RVU was 40.00 for both codes.

We do not disagree that survey respondents indicated that 34X06 and 34X04 represent comparable work; however, the correct statistical measure of comparability is the survey median, not the 25th percentile. All the discussion above for 34X04 applies to 34X06. Code 33534 is not a valid comparator code for several reasons, including the different valuation methodology and different typical patient. A ruptured aortic aneurysm is a catastrophic event with patients who present in varying degrees of hemorrhagic shock and are typically plagued by multisystem organ failure post-operatively.

Code 34X06 offers a less invasive approach for treatment, but remains an extremely intense service in an attempt to save the life of an actively dying patient. Code 34X06 captures significantly different

work compared to an elective aneurysm repair and includes the additional work of temporary balloon aortic occlusion as needed for hemodynamic instability as well as the significantly different, longer and more complex post-operative care.

We acknowledge that identifying comparator codes may be difficult if the focus is only on the survey code intraoperative and total time. Procedures which have high intensity and/or procedures with low intraoperative time, but high pre- and post-operative work are difficult to compare using these parameters. In this instance, it is more logical to consider intraoperative intensity to find comparator codes as support that the recommended work RVU is correct.

The table below was presented to the RUC to demonstrate that the median work RVU of 45.00 results in an intraoperative work intensity of 0.1429 that is relative to other highly intense services. This type of analysis allows for comparison of intraoperative work relativity across codes that have variable pre- and post-operative work.

We believe the discussion at the RUC about the inherent intense nature of 34X06 and appropriate relativity to other similarly intense procedures supports the RUC-recommended work RVU of 45.00.

СРТ	Descriptor	IWPUT	RVW	INTRA	Total Time
47130	Hepatectomy, resection of liver; total right lobectomy	0.1338	57.19	240	870
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	0.1345	33.36	180	477
33681	Closure of single ventricular septal defect, with or without patch;	0.1369	32.34	150	507
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion	0.1372	19.85	120	225
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	0.1386	24.05	120	367
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	0.1403	25.00	120	395
34X06	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-biiliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)	0.1429	45.00	178	735
43313	Esophagoplasty for congenital defect (plastic repair or reconstruction), thoracic approach; without repair of congenital tracheoesophageal fistula	0.1741	48.45	178	713
45126	Pelvic exenteration for colorectal malignancy, with proctectomy (with or without colostomy), with removal of bladder and ureteral transplantations, and/or hysterectomy, or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), or any combination thereof	0.1983	49.10	120	755

CPT Code 34X07

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 22.28 for CPT code 34X07.

This new code bundles preservice endograft planning, bilateral non-selective catheterization, endograft deployment, all angioplasty and/or stenting and all proximal and/or distal extensions from the level of the renal arteries down to the level of the aortic bifurcation, and all radiologic S&I.

We appreciate that CMS recognizes that a work RVU of 22.28 is the correct relative value for 34X07 within this family of EVAR codes and relative to other codes in the MPFS.

CPT Code 34X08

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 36.50 for CPT code 34X08. However, CMS requests comment on an alternative work RVU of 30.00 based on the survey 25th percentile. The agency notes that code 34X08 has identical intraservice and total times compared to code 34X02, but that the RUC-recommended work RVU of 36.50 for code 34X08 is higher than the RUC-recommended work RVU of 36.00 for code 34X02, which is the inverse of the relationship between codes 34X07 and 34X01 that describe the same procedures in a non-emergent state when a rupture does not take place. CMS seeks comment on whether the RUC-recommended work RVUs would create a rank order anomaly within the family by reversing the relationship between these paired codes and whether an increment of approximately 1.50 to 2.00 RVUs between the two code pairs is more appropriate.

We believe the work RVU for code 34X02 should be greater than the RUC-recommended value of 36.00. Of the four codes that CMS compares, code 34X02 will have the lowest utilization, and in fact, the survey median experience for 34X02 was zero. We presented separate summary data for surgeons with and without experience that showed a significantly higher median work RVU from the surgeons with experience. The RUC was not inclined to use the data from a subset of 19 survey responses for this rarely performed service, and instead determined to recommend the survey median from all survey respondents. The "weak link" in this set of two code pairs is not code 34X08, but instead code 34X02 because of performance rate. There is no rationale to suggest that the 25th percentile is a better measure of work for both codes simply because it ranks appropriately; the 75th percentile also accomplishes that goal. It is first important to look at the median work RVU for each code in comparison to similarly intense services, which is why the median for both codes is more appropriate.

Similar to the discussion above for 34X02, code 48000 is not a valid comparator code. A ruptured aortic aneurysm is a catastrophic event. These patients present in varying degrees of hemorrhagic shock and without rapid treatment, death is certain. Patients are critically ill post-procedure, typically plagued by multisystem organ failure and despite post-operative care, a portion of them still die. Despite advances in detection and treatment of aneurysmal disease, the rupture rate has remained relatively constant over the past two decades at roughly 15 percent of the total number of patients who present for abdominal aortic and iliac aneurysm repair. Code 34X08 offers a less invasive approach for treatment, but remains an extremely intense service in an attempt to save the life of an actively dying patient. Code 34X08 captures significantly different work compared to an elective aneurysm repair and includes the additional work of temporary balloon aortic occlusion as needed for hemodynamic instability, as well as the significantly different, longer and more complex post-operative care.

We acknowledge that identifying comparator codes may be difficult if the focus is only on the survey code intraoperative and total time. Procedures which have high intensity and/or procedures with low intraoperative time, but high pre-and post-operative work are difficult to compare using these parameters. In this instance, it is more logical to consider intraoperative intensity to find comparator codes as support that the recommended work RVU is correct.

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The table below was presented to the RUC to demonstrate that the median work RVU of 36.50 results in an intraoperative work intensity of 0.1411 that is relative to other highly intense services. This type of analysis allows for comparison of intraoperative work relativity across codes that have variable pre- and post-operative work.

We believe the discussion at the RUC about the inherent intense nature of 34X08 and appropriate relativity to other similarly intense procedures supports the RUC-recommended work RVU of 36.50.

СРТ	Descriptor	IWPUT	RVW	INTRA	Total Time
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	0.1335	29.40	150	457
47130	Hepatectomy, resection of liver; total right lobectomy	0.1338	57.19	240	870
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	0.1345	33.36	180	477
33681	Closure of single ventricular septal defect, with or without patch;	0.1369	32.34	150	507
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion	0.1372	19.85	120	225
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	0.1386	24.05	120	367
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	0.1403	25.00	120	395
34X08	Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting when performed, unilateral; for rupture including temporary aortic and/or iliac balloon occlusion when performed (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, traumatic disruption)	0.1411	36.50	120	677
43313	Esophagoplasty for congenital defect (plastic repair or reconstruction), thoracic approach; without repair of congenital tracheoesophageal fistula	0.1741	48.45	178	713
45126	Pelvic exenteration for colorectal malignancy, with proctectomy (with or without colostomy), with removal of bladder and ureteral transplantations, and/or hysterectomy, or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), or any combination thereof	0.1983	49.10	120	755

CPT Codes +34X09, 34X10, +34X11, 34X12

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 6.50 for code +34X09, 15.00 for code 34X10, 6.00 for code +34X11, and 12.00 for code 34X12.

We appreciate that CMS acknowledges that the RUC-recommended values for these four codes are correct within this family of EVAR codes and relative to other codes in the MPFS.

Global Period for Codes +34X13, +34812, +34X15, +34820, +34833, +34834, +34X19, +34X20. CMS requests comment on assignment of a 0-day global period to these eight codes, instead of the RUC-recommended add-on (ZZZ) global period. The global period assignment as add-on codes was not a RUC recommendation. The CPT proposal submitted in February 2016 proposed these eight codes as add-on codes was not a recommendation.

on because they never would be performed independent of another procedure. The subsequent review and revisions by the CPT Editorial Panel, which includes CMS and other third-party payer representatives never questioned the proposed add-on code assignment. In addition, add-on code assignment was confirmed as appropriate by CMS in October 2016 prior to the SVS conducting a RUC survey.

CMS notes that as add-on procedures, these eight codes would not be subject to the multiple procedure payment discount and is concerned that the total payment for these services will be increasing in the aggregate based on changes in coding that alter MPPR adjustments, despite the information in the surveys that reflects a decrease in the intraservice time required to perform the procedures, and a decrease in their overall intensity as compared to the current values.

The RUC considered changes in time and intraoperative intensity when determining an appropriate work RVU for each add-on code. The RUC also considered that all eight codes will be reported with the new CPT codes for ruptured endovascular aneurysm repair, which increases the intensity of the work of the add-on codes. When codes +34812, +34820, +34833, and +34834 were reviewed in 2000, these types of repair for challenging patients were not technically possible yet. Therefore, we believe that the new and revised codes represent more intensive work than originally considered in 2000, and the slight increase in intraoperative intensity that is consistent with the primary procedures is appropriate.

Four codes were revised and four codes are new. The RUC-recommended work RVUs for all eight codes are based on a magnitude estimation survey for add-on codes. CMS is considering adding back the preservice and immediate post-service work time, and increasing the work RVU of each code accordingly, using a building block methodology and then reducing them with the MPPR. It would be inappropriate to change the global period assignment for these codes and use a building block methodology to calculate a work RVU.

Multiple surgeries are separate procedures performed by a single physician or physicians in the same group practice on the same patient at the same operative session or on the same day for which separate payments may be allowed. Medicare pays for multiple surgeries by ranking from the highest MPFS amount to the lowest MPFS amount. When the same physician performs more than one surgical service at the same session, the allowed amount is 100 percent for the surgical code with the highest MPFS amount. The allowed amount for the subsequent surgical codes is based on 50 percent of the MPFS amount. The spirit of the multiple surgical reduction is to account for economies of scale in the pre-and post-service periods for stand-alone procedures. The MPPR works reasonably well for most 90 day global procedures with the reduction accounting for the overlapping service. The MPPR does not work for 0-day global procedures that have very little pre-and post-service work. The 50 percent reduction unjustly reduces the payment for the second procedure when there is little overlap of intraservice work.

We reiterate that these procedures are never performed alone and that the only correct global assignment is ZZZ. Changing them to add-on codes is not in line with standard CPT guidelines.

Valuation of Codes +34X13, +34812, +34X15, +34820, +34833, +34834, +34X19, +34X20

CPT Code +34X13

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 2.50 for CPT code 34X13. However, CMS requests comment on a change in global period from ZZZ to 000 and a

work RVU of 3.95 based on the RUC-recommended work RVU of 2.50 plus an additional 1.45 work RVUs. This additional work results from the addition of 38 total minutes of pre-service work time and 30 minutes of post-service work time based on a crosswalk to CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) as valued by using the building block methodology.

Code +34X13 will never be performed as a stand-alone service and therefore the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. In addition, the pre- and post-service work assigned to 37224 does not carry the intensity of the work related to exposure and closure for EVAR. Code 37224 is typically performed as an outpatient procedure and is also approved for office-based reporting. In contrast, almost all EVAR patients are inpatient.

The correct global period for +34X13 is ZZZ (add-on code) and the correct relative work RVU is 2.50.

CPT Code +34812

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 4.13 for CPT code 34812. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 6.48 based on maintaining the current 75 minutes of pre-service work time and the current 30 minutes of post-service work time, with a total work RVU of 2.35, added to the RUC-recommended work RVU of 4.13.

Code +34812 will never be performed as a stand-alone service and therefore the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34812 is based on a magnitude estimation survey as an add-on code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34812 is ZZZ (add-on code) and the correct relative work RVU is 4.13.

CPT Code +34X15

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 5.25 for CPT code 34X15. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 7.53 with the addition of 75 minutes of pre-service work time and 27 minutes of post-service work time to match CPT code 34833.

Code +34X15 will never be performed as a stand-alone service and therefore the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34X15 is based on a magnitude estimation survey as an add-on

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code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34X15 is ZZZ (add-on code) and the correct relative work RVU is 5.25.

CPT Code +34820

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 7.00 for CPT code 34820. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 9.46 based on maintaining the current 80 minutes of pre-service work time and the current 30 minutes of post-service work time.

Code +34820 will never be performed as a stand-alone service and therefore the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34820 is based on a magnitude estimation survey as an add-on code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34820 is ZZZ (add-on code) and the correct relative work RVU is 7.00.

CPT Code +34833

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 8.16 for CPT code 34833. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 10.44 based on maintaining the current 75 minutes of pre-service work time and the current 27 minutes of post-service work time.

Code +34833 will never be performed as a stand-alone service and therefore, the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34833 is based on a magnitude estimation survey as an add-on code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34833 is ZZZ (add-on code) and the correct relative work RVU is 8.16.

CPT Code +34834

CMS proposes to accept the RUC's broad-based multi-specialty consensus work RVU of 2.65 for CPT code 34834. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 5.00 based on maintaining the current 70 minutes of pre-service work time and the current 35 minutes of post-service work time.

Code +34834 will never be performed as a stand-alone service and therefore, the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34834 is based on a magnitude estimation survey as an add-on code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34834 is ZZZ (add-on code) and the correct relative work RVU is 2.65.

CPT Code +34X19

CMS proposes to accept the RUC's broad-based multi-specialty consensus work RVU of 6.00 for CPT code 34X19. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 8.35 with the addition of 70 minutes of pre-service work time and 35 minutes of post-service work time to match CPT code 34834.

Code +34X19 will never be performed as a stand-alone service and therefore the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34X19 is based on a magnitude estimation survey as an add-on code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34X19 is ZZZ (add-on code) and the correct relative work RVU is 6.00.

CPT Code +34X20

CMS proposes to accept the RUC's broad-based multi-specialty consensus work RVU of 7.19 for CPT code 34X20. However, CMS requests comment on a change in global period from ZZZ to 000 and a work RVU of 9.47 for CPT code 34X20 with the addition of 75 minutes of pre-service work time and 27 minutes of post-service work time to match CPT code 34833.

Code +34X20 will never be performed as a stand-alone service and therefore, the correct global period for this code is ZZZ (add-on). The pre-operative planning, evaluation, positioning, and work related to setting up a patient for a procedure performed under general anesthesia is inherent to the primary procedure that will be performed. Similarly, the immediate post-operative work is also inherent to the primary procedure. The RUC-recommended work RVU for +34X20 is based on a magnitude estimation survey as an add-on code. It would be inappropriate to change the global period assignment and use a building block methodology to calculate a work RVU.

The correct global period for +34X20 is ZZZ (add-on code) and the correct relative work RVU is 7.19.

Selective Catheter Placement (CPT codes 36215, 36216, 36217, and 36218)

Advancing Excellence and Innovation in Vascular Health

CPT code 36215 was identified in the 2016 CMS high expenditure screen and *also via the Harvard Valued – Utilization Over 30,000 screen.* CPT codes 36216, 36217 and 36218 were added as part of the family of services.

This code family was thoroughly reviewed by the RUC taking into account robust survey data, expert consensus, and comparison of relativity to other codes in the fee schedule. We believe that CPT codes 36215, 36216, and 36217 have been correctly valued by the RUC.

CMS is proposing to reduce the RUC-recommended value of 36217, a proposal we strongly disagree with. The RUC-recommended valuation included the following physician time components: pre-service time of 31 minutes, intra-service time of 60 minutes and immediate post-service time of 20 minutes.

The RUC engaged in significant discussion regarding the appropriate intra-service time for this procedure. The survey median intra-service time for this code was 50 minutes, only five minutes greater than the median intra-service time of 36216. The RUC recognized that CPT code 36217 includes the work of both 36215 (intra time = 30 minutes) and 36216 (intra time = 45 minutes) with some overlap of services. The RUC believed that the surveyed median times/values for 36215 and 36216 were appropriate but that the median intra-service time of 50 minutes for 36217 was not an appropriate increment to reflect the increased work and intensity of this service. To maintain incremental family values and times, the RUC justified a work RVU of 6.29 for 36217 comparing the surveyed code to the top key reference service CPT code 36247 Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family (work RVU = 6.29, intra time = 60 minutes) and agreed that since both services have identical intraservice time and comparable physician work, the work RVUs should be the same. This very similar third order catheterization code, which the specialties also perform, maintains an incremental work difference between the second order branch catheterization (36246) and the third order catheterization (36247) of 1.02 work RVUs with an intra-service time increment of 15 minutes. The recommended increment is appropriate and magnitude estimation of this increment is maintained throughout the family of services. The RUC therefore recommended the 75th percentile intra-service time of 60 minutes in order to accurately account for the physician work of placing a catheter in the third order branch, preserving the incremental, linear consistency between the work RVU and intra-service time within the family (i.e.15 minute time increment between first, second, and third order codes within the family).

The specialties believe that the times and work values for this code family are correct as recommended by the RUC. Therefore, we ask that CMS specifically reject its alternative value proposal and accept the original RUC recommendation for valuation of 36217 at 6.29 RVU with an intra-time of 60 minutes.

Treatment of Incompetent Veins (CPT codes 36470, 36471, 364X3, 364X4, 364X5, and 364X6)

CPT Codes 36470, 36471, 364X5, 364X6.

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU for these four codes.

We agree that the RUC recommendations are the appropriate relative values for these codes.

Codes 364X3 and 364X4.

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 3.50 for code 364X3 and 0.88 for code 364X4. However, the agency considered a work RVU of 4.38 for code 364X3 based on the RUC-recommended work RVU of 3.50 plus half of the RUC-recommended work RVU of code 364X4. The agency further considers assigning code 364X4 a status indicator of "bundled". CMS has concerns about the frequency that the current services include treatment of an initial vein (code 364X3) as compared to the treatment of initial and subsequent veins (codes 364X3 and 364X4 together). CMS believes it may be more accurate to describe these services through the use of a single code, as in the rest of this code family, instead of a base code and add-on code pair. Under this potential scenario, CMS looked at the RUC-recommended crosswalk and noted that the add-on CPT code 364X4 was estimated to be billed 50 percent of the time together with CPT code 364X3 and therefore, considered adding one-half of the RUC-recommended work RVU of code 364X4 (0.88) to the RUC-recommended work RVU of code 364X3 (3.50), resulting in a work RVU of 4.38.

CPT coding should define distinct physician work for appropriate reimbursement (both physician work and practice expense) and for data collection relative to outcome and risk. Bundling the add-on service as CMS suggests would undermine the premise of coding and relative reimbursement. Bundling the service as CMS suggests would also place a financial burden on the patients who do not require treatment of multiple veins because they would be paying 150 percent of what they should be paying - that is the payment-related reason for this coding structure. In addition, we do not understand the agency's statement "It may be more accurate to describe these services through the use of a single code, as in the rest of this code family, instead of a base code and add-on code pair". The structure of this code pair mirrors the existing code structure for ablation treatment of incompetent veins with radiofrequency (36475, 36476), laser (36477, 36478) and mechanochemical (36473, 36474). The new CPT code pair represents another new technology for ablation of incompetent veins as an alternative to existing treatment options.

The RUC-recommended work RVU of 3.50 for code 364X3 and 0.88 for code 364X4 represent the correct relative values for these codes.

Clarivein Kit for Mechanochemical Vein Ablation

In the CY 2017 MPFS Final Rule, CMS finalized work RVUs and direct PE inputs for two new codes related to mechanochemical vein ablation, CPT codes 36473 and 36474. Following the publication of the Final Rule, stakeholders contacted CMS and requested that a Clarivein kit supply item (SA122) be added to the direct PE inputs for CPT code 36474, the add-on code for ablation of subsequent vein(s). The SVS cannot support the CMS recommendation to include a second Clarivein kit in CPT Code 36474/add-on MOCA code at this time based on our internal discussions.

CPT Code 36473

The SVS requests a review of the bilateral surgery indicator for CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated), which was new for 2017. The indicator for this new code is "0" as shown below, but we believe that the correct indicator is "1". Similar to the other vein ablation treatment codes listed below, code 36473 can be performed on one or both legs.

HCPCS	Short Descriptor	Bilat Surg
36470	Injection therapy of vein	1
36471	Injection therapy of veins	1
36473	Endovenous mchnchem 1st vein	0
36475	Endovenous rf 1st vein	1
36478	Endovenous laser 1st vein	1

We appreciate this opportunity to bring this to your attention and hope this can be corrected.

CY 2018 Identification and Review of Potentially Misvalued Services

CMS is not proposing a new screen for CY 2018. CMS continues to believe that it is important to prioritize codes for review under the misvalued code initiative. As a result, the agency is seeking public comment on the best approach for developing screens, as well as what particular new screens they might consider. CMS will consider these comments for future rulemaking.

Dialysis

In the CY 2017 MPFS Final Rule, CMS included comments regarding appropriate values for the dialysis vascular access codes newly created in CY 2017 (CPT codes 36901 through 36909). The agency expressed concern that no data was included with the recommendations that would warrant increases to the work RVUs. At that time, CMS urged interested stakeholders to consider submitting robust data regarding costs for these and other services. Stakeholders have expressed concerns regarding the typical patient for these procedures as reflected in the information included in the RUC recommendations for CY 2017 and the importance of appropriate payment to ensure access to care for Medicare beneficiaries. Therefore, CMS is seeking additional comment, continuing to request robust data regarding the potentially misvalued work RVUs for CPT codes 36901 through 36909 and considering alternate work valuations for CY 2018, such as the RUC-recommended work RVUs from CY 2017, or other potential values based on submission of data through the public comment process.

These new dialysis codes involve obtaining new access as well as secondary access (36148 was removed and previously a reimbursed add-on code) to the dialysis circuit, while the codes CMS used as crosswalks (44388, 44403 and 44408) involve colonoscopy through an existing access (i.e. the enteric stoma). Comparing these endovascular codes involving a high flow arterialized fistula or graft to colonoscopy/ERCP is inappropriate. The typical patient for the dialysis code set is ASA 3 or 4. Chronic renal insufficiency is an inherently complex patient population. Crosswalking urgent dialysis procedures in a medically complex patient population to (typically) elective GI procedures is an improper comparison. The illness severity of the typical dialysis patient which impacts physician work was taken into context and discussed in significant detail during the RUC review process to assure relativity.

In addition, the use of direct crosswalks based only on intraservice time comparison or ratios of intraservice time do not appropriately account for the variation in technical skill, judgment, and risk inherent to these procedures. This argument is undermined further when the comparison codes are not similar clinically with regards to risk. The use of 43264 as a crosswalk for 36904 ignores the inherent differences in risk to the patient when working in the vascular system as opposed to the bile ducts.

We have no reason (or data) to believe that the vignettes used to survey this new family of dialysis codes were not appropriate. The survey respondents agreed that all nine vignettes were typical.

We urge CMS to accept the RUC's broad-based multispecialty consensus recommendations for this code set as follows:

- CPT code 36901, work RVU = 3.36
- CPT code 36902, work RVU = 4.83
- CPT code 36903, work RVU = 6.39
- CPT code 36904, work RVU = 7.50
- CPT code 36905, work RVU = 9.00
- CPT code 36906, work RVU = 10.42
- CPT code 36907, work RVU = 3.00
- CPT code 36908, work RVU = 4.25
- CPT code 36909, work RVU = 4.12

PE Inputs for Digital Imaging Services

CMS is seeking comments regarding whether or not the use of the professional PACS workstation would be typical in the following list of CPT and HCPCS codes: 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, and 76706, and HCPCS code G0365. The SVS recommends that the professional PACS workstation (ED053) be added as a direct PE input to the following CPT codes used by vascular surgery: 93880, 93882, 93925, 93926, 93930, 93931, 93970, 93971, 93975, 93976, 93978, 93979, 93990, and 76706 for 2018.

The digital conversion for all imaging modalities in medicine also includes vascular laboratories. The days of still images and VCR taped cine-loops have been replaced with high-tech digital PACS systems. This technology revolution has also resulted in exponential growth in the number and complexity of images to be reviewed per study. Interpretation now requires advanced computer hardware and software for accessing, reviewing, interpreting, documenting, and storing patient images and impressions. Interpreting physicians require access to these professional PACS systems to accurately interpret the ordered studies. The professional PACS direct practice expense inputs should be applied to the vascular lab codes outlined above.

CPT code 76706 *Ultrasound, abdominal aorta, real time with image documentation, screening study for abdominal aortic aneurysm* (AAA) was reviewed by the PE Subcommittee in October 2015 before the advent of the professional PACS workstation, but the technical PACS workstation (ED050) is included as a direct PE input and the description of the service specifies image documentation; therefore, the RUC recommends that a professional PACS workstation (ED053) be added to CPT code 76706.

HCPCS code G0365 may have been mistakenly included on this list as it already has a professional PACS workstation added for 2017 for 20 minutes of equipment time in the non-facility setting. CPT code 93965 was deleted.

Strapping Multi-Layer Compression (CPT codes 29580 and 29581)

CPT Code 29580

CMS proposes to accept the RUC's broad-based multi-specialty consensus work RVU of 0.55 for CPT code 29580 (Strapping; Unna boot). However, CMS is concerned with the pre-service time for 29580 compared to the RUC-recommended work RVUs. Compared to the specialty survey times, the RUC recommended a slight decrease (9 minutes) in pre-service time for CPT code 29580, with the intraservice and immediate post-service times remaining unchanged.

The survey pre-service times were reduced to the standard times for pre-time package 5 with one minute subtracted because local anesthesia is not used. Code 29580 is not typically reported with an E/M service; however, the preservice time includes significant patient evaluation as described in the preservice work description: Review chart with general medical and surgical history update, including current medications and allergies. Perform evaluation of neurological and vascular status of lower extremity, along with a dermatologic and musculoskeletal examination of the foot, ankle, and lower leg. Examine and measure the size and depth of the ulcer. Conduct proper patient screening to exclude those with deep infection, excessive edema, or excessively fragile skin. Communicate with the patient and/or family to explain the procedure, including a discussion of possible risks and complications. Verify all required instruments and supplies are available. Perform time out.

In contrast, the CMS comparator code 98925 (Osteopathic manipulative treatment (OMT); 1-2 body regions involved) is typically reported with an E/M service. This was taken into account by the specialty, the RUC, and CMS when the time in pre-time package 5 was reduced and maintaining the current work RVU was finalized for 98925. We do not agree that 98925 is a good comparator code.

In the summary of recommendation form for 29580, we cited two MPC codes that support the value: 46600 [Anoscopy; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)] [work RVU = 0.55, total time = 22 min] and 69210 (Removal impacted cerumen requiring instrumentation, unilateral) [work RVU = 0.61, total time = 17 min]. We also offered additional high volume and well-understood codes with similar intra-time as support: 69100 (Biopsy external ear) [work RVU = 0.81, intra-time = 12 min], 64566 (Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming) [work RVU = 0.60, intra-time = 10 min], and 11721 (Debridement of nail(s) by any method(s); 6 or more) [work RVU = 0.54, intra-time = 10 min].

The CMS alternative value is not appropriate. The RUC-recommended work RVU of 0.55 for 29580 is the correct relative value.

CPT Code 29581

CMS proposes to accept the RUC's broad-based multispecialty consensus work RVU of 0.60 for CPT code 29581 (Application of multi-layer compression system; leg (below knee), including ankle and foot). However, CMS considers an alternative value for 29581 based on the RUC-recommended work RVU increment between 29580 and 29581. While we agree that the slight work RVU increment is appropriate, as stated above, the RUC-recommended work RVU of 0.55 for 29580 is more than justified. Therefore, the RUC-recommended value of 0.60 for 29581 is also justified.

We do not agree that 97597 is an appropriate crosswalk for 29581. The work RVU for code 97597 was derived by a work neutrality calculation when codes 11040 and 11041 were deleted. The survey median

work RVU of 0.80 and 25th percentile work RVU of 0.70 were not considered valid for 97597 because work neutrality needed to be maintained.

In the summary of the recommendation form for 29581, we cited two MPC codes as additional support: 46600, [Anoscopy; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)] [work RVU = 0.55, total time = 22 min] and 69210 (Removal impacted cerumen requiring instrumentation, unilateral) [work RVU = 0.61, total time = 17 min]. We also offer additional high volume and well-understood codes with similar intra-time as support: 69100 (Biopsy external ear) [work RVU = 0.81, intra-time = 12 min], 12011 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less) [work RVU = 1.07, intra-time = 12 min], and 11901 (Injection, intralesional; more than 7 lesions) [work RVU = 0.80, intra-time = 13 min].

The CMS alternative value is not appropriate. The RUC-recommended work RVU of 0.60 for 29581 is the correct relative value.

Pre-service Clinical Labor for 0-Day and 10-Day Global Services

CMS is seeking comment specifically on whether the standard pre-service clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking. The RUC has standardized categories of time to "no use", "minimal use" and "significant use" of clinical staff. If a specialty requests more than zero minutes, compelling evidence/justification is required. For example, some recently reviewed 0-day codes that include some pre-service clinical staff time are actually major procedures, but have been assigned 0-day global status because of the variability for post operative care. There is no rationale that global period assignment for a major procedure impacts clinical staff work. Clinical staff time is necessary for patient clearance, pre-procedure meds, etc. The RUC reviews all requests for time greater than zero minutes carefully to be certain they are justified and ensures that there is relativity between similar procedures if extra time is allowed. SVS supports the RUC's current methodology of reviewing all requests individually.

Obtain Vital Signs Clinical Labor

CMS is proposing to assign five minutes of clinical labor time for 1,034 codes that include at least one minute in the "obtain vital signs" clinical staff task in the CMS work time file, regardless of the date of last review. CMS is also proposing to update the equipment times of the codes with this clinical labor task accordingly to match the changes in clinical labor time.

For codes that were not recently reviewed and for which they lack a breakdown of how the equipment time was derived from the clinical labor tasks, the agency is proposing to adjust the equipment time of any equipment item that matched the clinical labor time of the full service period to match the change in the "obtain vital signs" clinical labor time.

The proposal to immediately standardize 1,034 codes to five minutes is not relative, nor accurate. Instead, we recommend that CMS allows the RUC to continue to assign time for *obtain vital signs* as codes are reviewed. The time differences that CMS notes were assigned purposefully based on a review of required time and possible overlap with other codes and should be maintained.

Separate Payment for High Cost Medical Supplies

The SVS strongly recommends that CMS separately identify and pay for high cost disposable supplies using distinct HCPCS Level II codes, rather than bundle into the service described by CPT, so that these expenses may be monitored closely and paid appropriately. There are 33 disposable supply items with prices in excess of \$1,000 and bundled into the practice expense RVU for various CPT codes. SVS urges CMS to establish HCPCS codes for high cost supplies. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated similar to drug pricing.

Professional Liability Insurance Relative Value Units (PLI RVUs)

CMS is proposing to use the most recent professional liability insurance data for the proposed Malpractice RVUs for CY 2018. CMS is proposing several crosswalks (in Table 6) for which there was no premium data for at least 35 states, and specialties for which there were not distinct premium data in the rate filings, were cross-walked to a similar specialty. The SVS is concerned that the contractors were unable to get sufficient data from all fifty states for common specialties and questions the validity of the data being used to establish new rates for 2018.

We are also concerned about the use of a "blend" for certain specialty risk factors, rather than distinct non-surgical and surgical risk factors utilized in the past, for example cardiology and nephrology. According to the contractor report, there were insufficient premium data to justify the split this year for some specialties. For cardiology, the CMS contractor only collected dated from 12 states compared to 41 states in the previous year. The SVS recommends that all physician specialties continue to be split into surgical and non-surgical risk factors.

Vascular surgery shares many of the same CPT codes as cardiology and nephrology and thus is experiencing huge shifts in Malpractice RVUs because the CMS contractor did not obtain enough premium data. The SVS has serious concerns regarding the proposed dramatic valuation changes that are not indicative of what is occurring in the marketplace.

We urge CMS to require its contractor to obtain separate surgical and non-surgical premium data and recommend that CMS use the 2017 separate premium data for the affected specialties until more data can be obtained instead of using blended premiums for Malpractice RVU calculations.

Crosswalking Non-Physician Providers (NPP) to Allergy/Immunology

We disagree that all NPP specialties that were crosswalked to allergy/immunology are supported by data.

The AMA Physician Practice Information (PPI) Survey data used by CMS for calculating PE RVUs has shown that most of these NPP specialties have significantly lower premiums than allergy/immunology. For example, physical therapy and occupational therapy had rates that were less than 20 percent of the rate for allergy/immunology. In consideration of the fact that physical therapy and occupational therapy together account for 11 percent of all claims (MTUs), we believe this unsubstantiated crosswalk may significantly impact the Malpractice RVUs for all other specialties. We urge CMS to review the collected data, however minimal, for these specialties to determine if the crosswalk to allergy/immunology is supported before implementation of these crosswalks for future Malpractice RVU calculations.

<u>Proposed Modifications to the Satisfactory Reporting Criteria for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment</u>

CMS is proposing to modify the criteria it would apply to the data already submitted for the CY 2016 reporting period to determine whether an individual Eligible Professional (EP) or group practice has satisfactorily reported for purposes of avoiding the 2018 Physician Quality Reporting System (PQRS) payment adjustment.

Specifically, CMS is proposing to revise the previously finalized satisfactory reporting criteria for the CY 2016 reporting period to lower the requirement from nine measures across three NQS domains, where applicable, to only six measures with no domain or cross-cutting measure requirement.

The SVS appreciates CMS' willingness to lower the requirements for the 2018 payment year under the PQRS program. We also support CMS' argument that it should harmonize the final payment year of the PQRS program with the first reporting year requirements under the Merit-Based Incentive Payment System (MIPS) option under the Quality Payment Program (QPP). However, SVS would urge CMS to use the argument of a more supportive transition from PQRS to the QPP to support a change in PQRS requirements that align with the quality measures reporting requirements as articulated in the "Go at Your Own Pace" options for the 2017 reporting and 2019 payment years.

With this SVS recommendation, SVS members that reported on at least one quality measure in 2016 would be exempt from the two percent PQRS penalty in 2018. We believe this will allow more SVS members to have more resources in 2018 to invest in their QPP efforts because they will not be receiving the two percent PQRS penalty.

Value-Based Payment Modifier and Physician Feedback Program

CMS is proposing modifications to the Value-based Payment Modifier (VPM) policies for the CY 2018 payment adjustment period that would reduce the automatic downward adjustment for groups with 10 or more eligible professionals (EPs) to two percent and for groups between 2-9 EPs to one percent.

The SVS again appreciates CMS proposing to reduce the automatic downward adjustment for payment year 2018 under the VPM program. However, we would ask that CMS go even furthe by reducing their proposed two percent penalty to one percent for larger groups and to zero percent for smaller groups. Converting to the QPP program is very resource intensive and SVS members would be better served having smaller penalties under the VBM program in 2018 to fund their quality improvement activities.

MACRA Patient Relationship Categories and Codes

CMS is proposing that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018 should include the applicable HCPCS modifiers:

- X1 Continuous/Broad Services.
- X2 Continuous/Focused Services.
- X3 Episodic/Broad services.
- X4 Episodic/Focused Services.

• X5 - Only as Ordered by Another Clinician

as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). CMS anticipates there will be a learning curve with the use of the modifiers to report patient relationships, and believes that time is needed for clinicians to gain experience.

Therefore, for at least an initial period while clinicians gain familiarity, CMS is proposing that the HCPCS modifiers may be voluntarily reported on Medicare claims, the use and selection of the modifiers will not be a condition of payment and CMS will work on providing education.

The SVS supports CMS having the use of these patient relationship modifiers be voluntary in 2018 and not a condition of payment of said claims. The routine use of these modifiers will take time, not only regarding physician education, but also with the need to update computer billing systems and educate office and billing staff.

We are concerned that the descriptions used in these modifiers – focused services, board services, episodic, continuous – are vague and open to individual interpretation. CMS needs to create a document with specific definitions of these terms for each specialty regarding their main diseases treated or procedures performed during 2018. We would be happy to work with CMS on this for vascular diseases and conditions. We would also be happy to work with the agency to disseminate materials to SVS members and to have a webinar with CMS staff on this topic.

Request for Information on CMS Flexibilities and Efficiencies

The SVS signed onto a letter to Health and Human Secretary (HHS) Tom Price, MD with 10 other specialty societies regarding regulatory relief from the VPM, Meaningful Use (MU) of EHRs and PQRS programs, specifically requesting that 2018 penalties be minimized. We wanted to share these comments with CMS.

CMS Should Establish a VPM Adjustment of Zero for 2018

Authorized by Section 3007 of the Affordable Care Act ("ACA"), the purpose of the VPM program is to provide for upward or downward payment adjustments to a physician or group of physicians "based upon the quality of care furnished compared to cost".

Because the VPM program was enacted as part of the ACA, the program is subject to President Trump's first Executive Order issued on January 20, 2017, which directs HHS to "exercise all authority and discretion" available to it to "waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that imposes a penalty or regulatory burden on healthcare providers". The 2018 VPM program imposes a significant regulatory burden on physicians and the VPM adjustment of up to 4 percent authorized by the current regulations constitutes a considerable penalty.

Further, HHS has the authority under the governing statute to refrain from implementing the VPM in 2018 (or, stated differently, to establish a VPM adjustment of zero percent).

In fact, the governing statute specifically exhorts the Secretary to "coordinate" the VPM with "other similar provisions of [the Medicare Program]". In final rules implementing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS agreed to "zero out" the impact of the resource use component of the Merit Based Incentive Payment System (MIPS)-the successor to the VPM program-in 2019. The agency is according zero weight to the cost component of MIPS because the agency determined that physicians needed more time to understand the program. Yet, essentially the same (or similar) cost measures are used under the VPM program. Certainly a program that physicians do not understand in the MIPS 2017 performance year would also not be understood in the VPM 2016 performance program. Thus, establishing a "zero" VPM adjustment for 2018 is consistent with governing statute's language mandate to coordinate between the VPM program and other comparable programs.

Establishing a VPM adjustment of zero is not only consistent with the governing statute and the President's first Executive Order, it is also consistent with sound public policy. The VPM purports to compare physicians based on quality and resource use (costs). The statutory mandate requires that the cost component of the program "take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals such as to recognize that less healthy individuals may require more intensive interventions)". Yet, these factors are not adequately taken into account under the current VPM methodology, resulting in substantial geographic disparities that penalize physicians in population areas with poor health status as well as sub-specialists who treat those with more advanced disease or chronic conditions. Likewise, the current attribution methodology is fatally flawed, resulting, for example, in the designation of an ophthalmologist as a patient's primary care physician simply because the patient has an ophthalmic condition (e.g. macular degeneration or glaucoma) that requires frequent physician visits. In such cases, under the current attribution methodology, the costs of the patient's hernia repair and cardiac hospital admissions may be credited to the ophthalmologist. Similar absurdities are not uncommon for other specialists.

Finally, the fundamental redistributive impact of the program is unjustifiable: Based on the most recent data available, in 2016, nearly 40 percent of physician groups (5,418 TINs) received an automatic 2 percent downward VPM payment adjustment for failing to meet PQRS reporting criteria; while 128 groups received upward adjustments of either "+15.92 %" or "+31.84%". We are aware of physician groups that have received nearly \$1 million in additional payment as the result of application of the VPM. We believe that such a skewed result utterly fails to reflect the relative value of physician care to Medicare beneficiaries.

CMS Should Adopt Broader MU "Hardship Exemptions" To Maintain Consistency With MIPS Exemptions and Exceptions.

The statutory authority for the MU program specifically provides the Secretary with the authority to provide hardship exemptions, an authority that the Secretary has implemented since the inception of the program. We believe that, in light of the enactment of the 21st Century Cures Act (Pub. L. 114-225), the MU program should be suspended pending the adoption and implementation of new interoperability standards. In the alternative, the hardship exemptions provided under the MU program should be substantially expanded to be consistent with comparable exemptions under MIPS.

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Under the MU regulations currently in effect, in order to avoid penalties in 2018, a physician must use the 2014 or 2015 editions of CEHRT. However, in the 21st Century Cures Act (Pub. L. 114-225), Congress amended the certification requirements to provide that, on and after January 1, 2018, an EHR system cannot be certified if it has not met new interoperability standards; however, these standards have not yet been developed. Under Section 1848(o)(2)(A) of the Medicare Act, for the purpose of the MU payment adjustment, a meaningful user of CEHRT is defined as an eligible professional who, for the applicable EHR reporting period (i.e. 2016, in the case of the 2018 MU adjustment) meets the following requirement, among others:

(i) INFORMATION EXCHANGE.—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during [the performance] period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination. [Emphasis added]

It was the lack of "law and standards applicable to the exchange of information" that resulted in enactment of the interoperability provisions of the 21st Century Cures Act. In other words, the MU penalties appear to presume a level of interoperability that has not yet been achieved and that cannot be achieved until the new interoperability standards are implemented.

As a practical matter, what sense does it make to penalize physicians for failing to install or make "meaningful use" of CEHRT that, based on a Congressional mandate, will be outdated by the time the penalty is imposed? Under these circumstances, we believe that the Secretary should determine that the 2018 edition of CEHRT is required for the purposes of the MU program and that application of the MU adjustments are suspended pending implementation of the new interoperability standards.

Barring this type of relief, we strongly urge the expansion of the hardship exemptions to at least be consistent with the various exemptions and exceptions provided to low volume physicians ¹, small practices, and hospital-based physicians under MIPS. MACRA regulations exempt from MIPS physicians and practices that meet the "low volume threshold" from the Advancing Care Information (ACI) and other MIPS requirements, because the agency found that compliance would constitute a hardship for these practices. The ACI requirements are the successor to today's MU program requirements, but are considerably less onerous. It is within the authority of the Secretary to determine that the same "low volume" threshold should be used to identify those physicians for whom compliance with the MU requirements would be a hardship. A similar rationale supports providing a hardship exemption for any physician who is in a "small practice" as defined by the MACRA regulations (a practice of 15 or fewer physicians and other clinicians. ²

Our rationale for small practices and practices located in rural areas and in HPSAs is grounded in the resource constraints that these MIPS eligible clinicians face. This rationale is especially compelling given

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¹ The final MIPS regulations substantially expanded the availability of the MIPS low volume exception as compared with the proposed rule, such that those physicians and other eligible professionals with less than or equal to \$30,000 in Medicare Part B annual allowed charges or less than or equal to 100 Medicare patients per year are exempt from MIPS.

² Under the final MACRA regulations, such small practices are subject to less stringent scoring under the Clinical Practice Improvement Activity (CPIA) category of MIPS. In finalizing these more relaxed CPIA requirements for small practices, the agency states:

We note that, while MU exemptions historically have been based on individual hardship exemption applications, the statute does not require an application process, but only that determinations be made on a "case-by-case" basis. A physician's eligibility for a hardship exemption as a low volume physician, member of a small practice or MIPS eligible hospital-based physician can be determined by CMS based on the physician's claims history in 2016. Therefore, we believe that the expanded hardship exemptions described above could be implemented by CMS in 2018.

CMS has the Authority to Make PQRS More Rational and Fair

The statutory authority for the PQRS payment adjustments specifies the percentage adjustment to be applied to a physician's payments if that physician fails to meet PQRS reporting requirements. For 2018, the statute states that the Secretary "shall" apply a payment adjustment of 2 percent to the payments of physicians who fail to meet PQRS reporting requirements.

CMS has the flexibility to make PQRS reporting considerably less onerous and to thereby minimize the number of physicians who are subject to PQRS penalties. For example, the current regulations require physicians to report on nine quality measures in three "domains" in order to avoid negative PQRS payment adjustments. This nine measure/three domain requirement has created a number of hardships for physicians, especially for specialists, who often lack clinically appropriate quality measures. In part, as the result of the nine-measure/three domain reporting requirement, almost half of all physicians were subject to the PQRS payment adjustment in 2016. And because those who do not meet PQRS reporting requirements are also subject to a 2 percent VBM adjustment, the impact of the nine-measure/three domain requirement is essentially doubled.

The governing statute does not specify the number of measures required to be reported. The successor of the PQRS program – the quality component of MIPS – reduces the quality reporting requirement from nine measures to six measures. In the first year of MIPS, reporting on even one measure allows a physician to avoid penalties. We strongly urge you to adopt a similar relief for the purpose of the PQRS adjustment for 2018.

Another example of an administrative burden for vascular surgeons are all the requirements that must be met in order for moderate sedation to be billed correctly. These include the following:

that each activity requires at least 90 days and may not necessarily be conducted in parallel, with time allocated to pre-planning and post-planning, which would impact the practice's limited resources

Federal Register /Vol. 81, No. 214 at 77317 (November 4, 2016). Substantially greater resources are necessary to install CEHRT and implement a program that meets MU requirements than to meet the MIPS CPIA requirements. Therefore, a practice that meets the MIPS small practice definition (15 physicians or fewer) should be entitled to a MU hardship exemption.

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- There must be a documented independently trained observer if a surgeon is doing the procedure. This person must be a qualified professional with no other duties during the procedure other than monitoring the patient.
- There must be a documentation for the start time when sedating agents are administered and a stop time when the procedure is complete, when the patient is stable for recovery status and the physician ends personal continuous face-to-face time with the patient.
- There must be documentation for pre-procedure assessment, patient's response to sedating agents and a periodic assessment of the patient during the procedure such as monitoring of oxygen saturation, heart rate and blood pressure.

To help ensure that billing is correct, the SVS recommends one common template for all of the above so that information is accurate and easily found for reimbursement purposes.

With all the burdens that physicians are presently facing, SVS members have written a series of articles on "burnout". To quote one of the articles: "burnout is real and is impacting the health, well-being and careers of vascular surgeons. Burnout places both the surgeon and the patient at risk for a poor outcome. Burnout influences medical student and resident career choices. Burnout can no longer be ignored – doing nothing is not an option". Decreasing administrative burden is an important solution in addressing burnout in physicians.

Collecting Data on Resources Used in Furnishing Global Services

As stated in comments on the CY 2017 MPFS Final Rule, the SVS appreciated the changes that CMS made to the collection of data on global services, including: finalizing the use of CPT code 99024, Global Post-Operative Visits to collect data, using only post-operative codes with high allowed charges and high volumes, limiting reporting to groups of 10 or more in 10 states and not withholding five-percent of payment on MPFS services for not reporting.

However, the SVS did not support an additional survey of practitioners to obtain data to supplement the agency's claims-based data collection. Also, we continue to be concerned that data collection would be based on "typical" post-operative visits, which would not take into account a wide variety of activities. For example, "typical" medication management after one procedure might be just pain and antibiotic management, but another "typical" medical management might be for pain, hypertension, diabetes, deep vein thrombosis, electrolytes and anticoagulation management.

In addition, we still believe that data collection will create undue administrative burdens for physicians and Medicare beneficiaries in the states and practices that would be required to provide data to CMS. Another way the agency could provide regulatory relief to physicians would be a decision to not collect data on surgical post-operative services.

Finally, the SVS is at a loss regarding the lack of information on this issue in the CY 2018 MPFS Proposed Rule. With no update in the Proposed Rule on the 10- and 90-day global codes to be reported starting July 1, 2017, are these the same codes that physicians should use for reporting in 2018? Should we assume that the data collection has been postponed or is being reconsidered? **We would appreciate clarification from CMS on this issue**.

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The SVS appreciates the opportunity to provide comments on this Proposed Rule. If you have any questions or need additional information, please contact Pamela Phillips, Director of the SVS Washington Office at pphillips@vascularsociety.org or 202-787-1220.

Sincerely,

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