



September 11, 2017

Via Electronic Submission

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs [CMS-1678-P]—RIN: 0938-AT03

Dear Administrator Verma:

The Society for Vascular Ultrasound (“SVU”) thanks the Centers for Medicare and Medicaid Services (“CMS” or the “Agency”) for this opportunity to comment on the proposed changes to the Hospital Outpatient Prospective Payment System (“HOPPS”) for calendar year (“CY”) 2018 (the “Proposed Rule”).¹ SVU is a professional society comprised of over 5,700 vascular technologists, sonographers, nurses, and physicians who provide a variety of high-quality vascular ultrasound services² to Medicare beneficiaries in all sites of care, including hospital outpatient departments, freestanding clinics, and increasingly Ambulatory Surgical Centers (“ASCs”).

Vascular ultrasound is a critical diagnostic tool that uses sound waves to obtain images of internal anatomic structures. It offers a highly sensitive, non-invasive, and low-cost means of examining internal vessels. Vascular ultrasound utilization not only saves Medicare dollars, but also reduces the risks involved with other more expensive or invasive diagnostic imaging modalities, which may present more significant morbidity and mortality risks. With this in mind, SVU offers these comments on the Proposed Rule from the perspective of vascular ultrasound.

¹ 82 Fed. Reg. 33558 (Jul. 20, 2017).

² Such services and related codes include: 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, G0365, and 76706 (formerly G0389).

I. Overview of SVU's Comments

In summary, SVU presents for CMS' consideration the following comments to the Proposed Rule regarding our concerns with the proposed imaging without contrast APC groupings for CY 2018:

- SVU is deeply concerned by CMS' proposed restructuring of the Imaging without Contrast APC's for CY 2018, which, if finalized, would have an unprecedented, devastating impact on reimbursement for vascular ultrasound services in both the hospital outpatient department and physician fee schedule sites of care. Because we believe that there are a number of issues raised by the proposal, we urge CMS to maintain the groupings for CY 2018 that it finalized for CY 2017.
- As a threshold matter, the proposed Imaging without Contrast APCs appear to mistakenly include numerous contrast procedures.³ In our view, the inclusion of these contrast procedures in the Imaging **without** Contrast APCs disturbs the resource homogeneity of the groupings. Further, their inclusion also appears to be inconsistent with the statutory requirement that procedures utilizing contrast agents be classified separately from those that do not.⁴
- SVU is also deeply concerned by CMS' proposal to, among other things, effectively reverse its policy, finalized for CY 2017, to include echocardiography in the Imaging without Contrast APCs and, once again, create a separate APC for certain echocardiography procedures.⁵ In our view, this proposal to move echocardiography procedures to a separate APC level for CY 2018 despite the Agency's recognition that there is "no compelling reason to separate echocardiography procedures, an imaging test of the heart, from other imaging tests in the APC groupings" appears inconsistent with its prior consolidation policy. Accordingly, SVU strongly urges CMS to maintain the existing Imaging without Contrast APCs as developed for CY 2017. In the alternative, if echocardiography services are to effectively have their own APCs, we urge CMS to develop vascular ultrasound specific APCs. We believe that CMS should have a

³ **APC 5522:** 74210 (Contrast x-ray exam of throa); 74220 (Contrast x-ray esophagus); 74290 (Contrast x-ray gallbladder); **APC 5523:** 74246 (Contrast x-ray uppr gi tract); 74247 (Contrast x-ray uppr gi tract); 74249 (Contrast x-ray uppr gi tract); 74270 (Contrast x-ray exam of colo); 74280 (Contrast x-ray exam of colo); 74283 (Contrast x-ray exam of colo); 74400 (Contrast x-ray urinary tract); 74410 (Contrst x-ray urinary tract); **APC 5524:** 74415 (Contrast x-ray urinary tract); 74425 (Contrast x-ray urinary tract); 74430 (Contrast x-ray bladder); 73040 (Contrast x-ray of shoulder); 73115 (Contrast x-ray of wrist); **APC 5525:** 62302 (Myelography lumbar injection); 62303 (Myelography lumbar injection); 62304 (Myelography lumbar injection); 62305 (Myelography lumbar injection); 70010 (Contrast x-ray of brain); 70015 (Contrast x-ray of brain); 72240 (Myelography neck spine); 72255 (Myelography thoracic spine); 72265 (Myelography l-s spine); 72270 (Myelography 2/> spine regions); 73085 (Contrast x-ray of elbow); 73525 (Contrast x-ray of hip); 73580 (Contrast x-ray of knee join); 73615 (Contrast x-ray of ankle); 74420 (Contrast x-ray urinary tract); 75559 (Cardiac mri w/stress img).

⁴ SSA § 1833(t)(2)(G).

⁵ Once the contrast procedures, including the myelography procedures, are removed from the proposed fifth APC level and appropriately placed in the Imaging with Contrast APCs, only 15 codes would remain, 11 of which are echocardiography procedures.

consistent policy with respect to either consolidation or separation of clinical services in different modalities.

- Although SVU strongly believes that CMS should maintain the existing APCs finalized in CY 2017, if the Agency nevertheless decides to move forward with its proposal to further restructure the APCs, the groupings must be clinically and resource similar.⁶ To that end, SVU has provided CMS with alternative APCs that more appropriately group, relative to CMS' proposed Imaging without Contrast APCs for CY 2018, imaging services that are comparable both clinically and with respect to resource use. We provide these various alternatives in an attempt to anticipate what could be various positions by CMS with respect to consolidation or separation of different modalities of service. Given the complexity of the issues involved, it again seems to be most appropriate to maintain the groupings, as they currently exist, for CY 2018 and to further study the issue.

These comments are addressed in greater detail below. We thank you in advance for your consideration.

II. Further Restructuring of the Imaging without Contrast APCs: Our Significant Concerns with the Proposed Classifications

SVU is deeply concerned by the devastating impact that CMS' proposed restructuring of the Imaging without Contrast APCs would have on vascular ultrasound codes and Medicare beneficiaries' access to vascular services. In the HOPPS setting alone, the proposed restructuring would result in an estimated \$65 million cut in reimbursement for vascular ultrasound procedures, with the most critical codes experiencing a \$76.00 (or 33%) reduction per procedure. This would result in inadequate Medicare reimbursement for vascular ultrasound services both in the HOPPS and Physician Fee Schedule ("PFS") sites of care, including community-based vascular ultrasound laboratories and individual physician offices, because the Deficit Reduction Act requires the use of HOPPS reimbursement rates to replace PFS payments for the technical component of imaging services, where the HOPPS reimbursement rates are lower than the PFS rates. We fear that the unintended consequences of the proposed changes will be to limit beneficiaries' access to vascular ultrasound and increase utilization of more expensive alternative diagnostic procedures, many of which involve radiation exposure, with their attendant risks.

Further, we are concerned that the proposed restructuring for CY 2018 is inconsistent with CMS' prior consolidation policy, as we understood it, and that the rationale for the further restructuring supplied in the Proposed Rule does not appear to support the Agency's actions, raising significant procedural and substantive concerns. Accordingly, SVU strongly urges CMS to refrain from implementing the proposed Imaging without Contrast APCs so that the Agency and stakeholders can explore these issues further. If, however, CMS nevertheless decides to move forward with its proposal to further restructure the APCs, the groupings must be clinically and resource similar. As presently proposed, the Imaging without Contrast APCs place significantly different services in the same APCs and quite similar services different APCs. Therefore, below, SVU has provided CMS with alternative APC groupings that, in our opinion, more appropriately group clinical and resource similar imaging services, relative to CMS' proposed groupings for CY 2018.

⁶ See SSA § 1833(t)(2)(B).

The specifics of SVU's clinical and resource-based concerns are explained in greater detail below.

A. The Proposed Imaging without Contrast APCs Mistakenly Include Contrast Procedures

As a threshold matter, the proposed Imaging without Contrast APCs appear to mistakenly include numerous contrast procedures.⁷ With respect to resource homogeneity in the imaging APCs, CMS has explained that the “[a]ssignment of an imaging service to a specific APC within each of the[] two imaging series (with or without contrast) depends upon the use (or non-use) of a contrast agent”⁸ Accordingly, the inclusion of these contrast procedures in the Imaging **without** Contrast APCs disturbs the resource homogeneity of the groupings, contrary to the statutory requirement that APC groupings be comparable with respect to the use of resources.⁹ Further, the inclusion of contrast procedures in the Imaging without Contrast APCs appears inconsistent with the statutory requirement that procedures utilizing contrast agents be classified separately from those that do not.¹⁰

Accordingly, because we believe the proposed inclusion of these contrast procedures in the Imaging without Contrast APCs may have been unintentional, we strongly urge CMS to move these codes to the Imaging with Contrast APCs for CY 2018.

B. The Proposed Imaging without Contrast APCs Appear Inconsistent with CMS' Prior Consolidation Policy

SVU has previously tried to support CMS in its policy to consolidate imaging procedures into clinically and resource similar APC groupings based on the use or non-use of contrast agents and without regard to the underlying imaging modality used or organ examined. Consistent with CMS' policy, SVU and other stakeholders supported the integration of echocardiography procedures, which are diagnostic ultrasounds of the heart, with other diagnostic imaging procedures, including vascular ultrasound, which is a diagnostic procedure of the veins and arteries using ultrasound, MRI, X-Ray, and CT.

If CMS is to continue to implement a consolidation policy, we believe that echocardiography should be included in that consolidation policy. Echocardiography services without contrast are very much clinically comparable to vascular and other complex diagnostic ultrasound services.

⁷ **APC 5522:** 74210 (Contrast x-ray exam of throa); 74220 (Contrast x-ray esophagus); 74290 (Contrast x-ray gallbladder); **APC 5523:** 74246 (Contrast x-ray uppr gi tract); 74247 (Contrast x-ray uppr gi tract); 74249 (Contrast x-ray uppr gi tract); 74270 (Contrast x-ray exam of colo); 74280 (Contrast x-ray exam of colo); 74283 (Contrast x-ray exam of colo); 74400 (Contrast x-ray urinary tract); 74410 (Contrst x-ray urinary tract); **APC 5524:** 74415 (Contrast x-ray urinary tract); 74425 (Contrast x-ray urinary tract); 74430 (Contrast x-ray bladder); 73040 (Contrast x-ray of shoulder); 73115 (Contrast x-ray of wrist); **APC 5525:** 62302 (Myelography lumbar injection); 62303 (Myelography lumbar injection); 62304 (Myelography lumbar injection); 62305 (Myelography lumbar injection); 70010 (Contrast x-ray of brain); 70015 (Contrast x-ray of brain); 72240 (Myelography neck spine); 72255 (Myelography thoracic spine); 72265 (Myelography l-s spine); 72270 (Myelography 2/> spine regions); 73085 (Contrast x-ray of elbow); 73525 (Contrast x-ray of hip); 73580 (Contrast x-ray of knee join); 73615 (Contrast x-ray of ankle); 74420 (Contrast x-ray urinary tract); 75559 (Cardiac mri w/stress img).

⁸ 81 Fed. Reg. at 79628.

⁹ See SSA § 1833(t)(2)(B).

¹⁰ SSA § 1833(t)(2)(G).

Echocardiography and vascular ultrasound services typically involve sonographers primarily credentialed by two national credentialing bodies, with identical standards and requirements, in laboratories accredited by the same organizations under highly comparable standards, using often the exact same ultrasound machines, and not infrequently involving the exact same sonographers, who often provide both sets of services. In fact, vascular ultrasound often requires additional physiologic testing equipment, adding to the expense of providing the services in many locations. In addition, both sets of services have complex clinical protocols relative to other imaging services and frequently involve the acquisition of multiple images/measurements, requiring longer service times, depending on the amount of disease or other complicating factors present. Moreover, the resources associated with echocardiography services are not in any way meaningfully distinguishable from the resources required for other complex ultrasound services. In addition, the various services have highly comparable service times, with vascular ultrasound services not infrequently having longer service times.

In implementing its consolidation policy, CMS has appeared to agree with these points. CMS stated in the CY 2017 Proposed and Final Rules that “imaging services, which are diagnostic tests including x-rays, ultrasounds (including echocardiography), CT scans, and MRIs are sufficiently clinically similar for APC grouping purposes,” and there is “**no compelling reason to separate echocardiography procedures, an imaging test of the heart, from other imaging tests** in the APC groupings.”¹¹

However, CMS' proposal to move from 4 APC levels to 5 APC levels in CY 2018, effectively creating a separate APC for certain echocardiography procedures, leaves us uncertain as to whether there has been a change in CMS' policy. Indeed, once the contrast procedures, including the myelography procedures, are removed from the proposed Level 5 APC and appropriately placed in the Imaging with Contrast APCs, only 15 codes would remain, 11 of which are echocardiography procedures. As such, we are concerned by what appears to be a decision to effectively reverse the Agency's prior consolidation policy, at least for echocardiography services, without similarly separating out in distinct APCs other imaging services.

The explanation offered for the addition of the proposed Level 5 APC in the Proposed Rule is that the Agency “believe[s] the data support splitting the current Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency low cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency high cost services.”¹² However, we believe that this statement may indicate that CMS was not aware of the effect of the proposed regroupings. We do not believe that this rationale actually explains the distinctions drawn between Level 4 and Level 5 services. For example, this supplied rationale regarding the frequency and cost of procedures does not align with the Agency's proposal to create a fifth APC level almost exclusively composed of echocardiography procedures that CMS has recognized as similar, both clinically and with respect to resource use, to other diagnostic ultrasound procedures in the Level 4 APC. In addition, under the proposed restructuring, certain lower cost echocardiography codes would be elevated to the new Level 5 APC¹³ while certain low frequency higher cost non-echocardiography codes would remain in the Level 4 APC.¹⁴

¹¹ 81 Fed. Reg. at 79629 (emphasis added).

¹² 82 Fed. Reg. at 33609.

¹³ See e.g., 76825 (echo exam of the fetal heart) and 76826 (echo exam of the fetal heart).

¹⁴ See e.g., 74470 (x-ray exam of kidney lesion) and 70134 (x-ray exam of middle ear).

Accordingly, we are uncertain as to how the proposed groupings are consistent with CMS' prior consolidation policy, as we understood it, or a policy of placing high frequency low cost services in Level 4 and low frequency high cost services in the Level 5 APC.

Accordingly, SVU strongly urges CMS to maintain the existing Imaging without Contrast APCs structure and refrain from any further restructuring, including the addition of a fifth APC level, so that the Agency and stakeholders can explore these issues further. We believe that better APC groupings can be developed if CMS provides us and others with the opportunity to present and discuss alternative options once CMS clearly articulates its intended policy for assigning imaging procedures to APCs.

C. Clinically and Resource Comparable Alternative Imaging without Contrast Groupings

As discussed above, SVU strongly believes that CMS should not restructure the Imaging without Contrast APCs for CY 2018, and instead, should maintain the existing APCs finalized in CY 2017. If, however, CMS nevertheless decides to move forward with its proposal to further restructure the APCs, the groupings must be clinically and resource similar.¹⁵ To that end, SVU has discussed various alternative APCs with CMS that, in our view, more appropriately group imaging services that are comparable both clinically and with respect to resource use, relative to CMS' proposed Imaging without Contrast APCs for CY 2018.

Specifically, we have discussed three alternatives: a "2 Level" approach for structuring APCs specific to vascular ultrasound procedures and a "4 Level" approach and a "5 Level" approach for structuring the Imaging without Contrast APCs.¹⁶

Because the proposed groupings for CY 2018 suggest that CMS may be considering a departure from its prior consolidation policy, we offer a 2 Level APC approach specific to non-invasive diagnostic vascular ultrasound procedures. SVU appreciates that there may be potential benefits associated with more specific APC groupings, including fewer 2 times rule violations and greater stability with respect to annual reimbursement for individual procedures, and we would be happy to work with CMS and other stakeholders to develop an APC structure in which the groupings for diagnostic imaging services are, once again, specific to the modalities used and the organs studied. However, in our view, the Agency should not maintain its consolidation policy for some imaging services while making exceptions for other imaging services. Accordingly, we ask that in the CY 2018 Final Rule, CMS clarify its grouping policy for the imaging APCs, and, if the Agency would

¹⁵ See SSA § 1833(t)(2)(B).

¹⁶ Like CMS' proposal for CY 2018, both the Level 4 and the Level 5 alternative groupings include a 2 times rule violation in the Level 1 APC. Both also include 2 times rule violations in the highest APC level (*i.e.*, Level 4 or Level 5) for each respective alternative. As CMS is aware, the Agency is permitted to make exceptions to the 2 times rule based on the following criteria: (1) resource homogeneity; (2) clinical homogeneity; (3) hospital outpatient setting utilization; (4) frequency of service (volume); and (5) opportunity for upcoding and code fragments. Just as CMS has concluded that its proposed Level 1 APC grouping satisfies the exceptions to the 2 times rule, SVU also believes that the potential 2 times rule violations in its alternative groupings satisfy the clinical and resource homogeneity and frequency of service exceptions to the 2 times rule. Further, we believe that the composition of the highest APC level in each of these two alternatives is generally consistent with CMS' stated policy of consolidating relatively low utilization high cost codes into the highest APC level, contributing the 2 times violation.

like to depart from its prior consolidation policy, we ask that CMS provide notice and solicit comments on such a proposal to allow for input from stakeholders.

As the names suggest, the “4 Level” approach organizes clinically and resource comparable APCs, as such concepts have been interpreted under CMS' consolidation policy, into four levels, similar to the existing 4 Level APC structure CMS currently uses for imaging without contrast services. SVU believes that the existing 4 Level APC structure for ultrasound services is most consistent with the policies CMS has previously articulated. We do, however, offer an alternative 4 Level structure based on the updated geometric mean costs for CY 2018. Under this alternative 4 Level structure, most limited vascular ultrasound services would remain in Level 2. Similarly, the complete/bilateral vascular ultrasound studies would remain in Level 3.

In addition, notwithstanding our questions regarding the addition of a fifth APC level to the Imaging without Contrast APC groupings, as proposed, we also offer a “5 Level” approach for CMS' consideration. Under this alternative 5 Level structure, the limited vascular ultrasound services would be placed, depending on their geometric mean costs, in Level 2 or Level 3. Finally, the complete/bilateral vascular ultrasound services would be placed in Level 4.

* * *

We thank you for your consideration of these comments to the Proposed Rule. We look forward to continuing to work with CMS to improve the health of Medicare beneficiaries.

Respectfully submitted,



Joseph P. Hughes, RVT, RVS, FSVU
President
Society for Vascular Ultrasound



Kelly Byrnes, BS, RVT, FSVU
Chair, Advocacy Committee
Society for Vascular Ultrasound