

September 11, 2017

Via Electronic Submission

Seema Verma, Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services *Attn:* CMS-1676-P P.O. Box 8013 Baltimore, MD 21244-1850

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee
Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings
Program Requirements; and Medicare Diabetes Prevention Program
[CMS-1676-P]—RIN: 0938-AT02

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 "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B" for calendar year ("CY") 2018 (the "Proposed Rule"). 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 services to Medicare beneficiaries.

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 organs and vessels. 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.

In summary, SVU presents for CMS' consideration the following comments to the Proposed Rule:

• Clinical Labor Direct PE Inputs. SVU strongly supports CMS' proposal to update the minutes assigned to the "Obtain vital signs" clinical labor activity from three minutes to five minutes for several vascular ultrasound codes. We agree that the variances in the minutes assigned to this

¹ 82 Fed. Reg. 33959 (Jul. 21, 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 76707 (formerly G0389).

clinical labor activity appear to be based on changes in review standards over time rather than differences in practice, which is "detrimental to relativity among PFS services."

- **Professional PACS Workstation.** SVU appreciates CMS' solicitation of "comments regarding whether or not the use of the professional PACS workstation would be typical in [vascular ultrasound codes]." Although we applauded CMS' recognition in the CY 2017 Final Rule that the professional PACS workstation is an essential component of diagnostic imaging procedures following the switch from film to digital technology, we were deeply concerned by the Agency's decision not to include this new input for vascular ultrasound codes that also use professional PACS workstations. SVU strongly urges CMS to add the professional PACS workstation input to all vascular ultrasound codes for CY 2018.
- Variable Maintenance Factor Assumption. SVU applauds CMS' recognition that "the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment" and appreciates the Agency's willingness to continue to "investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items." Further, we strongly urge CMS to make the "maintenance cost" factor in the "equipment cost per minute" calculation variable, similar to other assumptions in the calculation. Unfortunately, the existing "one size fits all" rate assumption fails to appreciate the significant costs associated with the maintenance of highly technical and particularly complex equipment items, such as the PACS.

These concerns are addressed in greater detail below. We thank you in advance for your consideration of SVU's comments.

I. Clinical Labor Direct PE Inputs

SVU strongly supports CMS' proposal to update the minutes assigned to the "Obtain vital signs" clinical labor activity from three minutes to five minutes for several vascular ultrasound codes. In the Proposed Rule, CMS explains that the Agency traditionally assigned a clinical labor time of three minutes for the "Obtain vital signs" clinical labor activity, but over time, that number of minutes increased to five minutes as newer codes were reviewed. We agree that these differences appear to be attributed to variances review standards over time rather than changes or differences in practice. As such, these variances are "detrimental to relativity among PFS services," and SVU strongly urges CMS to finalize its proposal to "preserve relativity among the PFS codes [by] . . . assign[ing] 5 minutes of clinical labor time for all codes that include the "Obtain vital signs" task, regardless of the date of last review."

II. Professional PACS Workstation

SVU appreciates CMS' solicitation of "comments regarding whether or not the use of the professional PACS workstation would be typical in [vascular ultrasound codes]." Although we

³ 82 Fed. Reg. at 33960.

⁴ 82 Fed. Reg. at 33959.

⁵ See 80 Fed. Reg. 70886, 70896 (Nov. 16, 2015).

⁶ 82 Fed. Reg. at 33959.

⁷ *Id.* at 33960.

⁸ *Id*.

⁹ *Id.* at 33959.

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applauded CMS' recognition in the CY 2017 Final Rule that the professional PACS workstation is an essential component of diagnostic imaging procedures following the switch from film to digital technology, we were deeply concerned by the Agency's decision not to include this new input for vascular ultrasound codes that also use professional PACS workstations. Accordingly, for the reasons outlined in the letter we submitted in advance of the CY 2018 Proposed Rule and also below, SVU strongly urges CMS to include the professional PACS workstation input in vascular ultrasound codes for CY 2018.

For CY 2017, CMS announced a set of four requirements for purposes of determining which codes were eligible to receive the new professional PACS workstation input. In particular, for the new professional PACS workstation input to be added to the PFS database as a direct PE input for a service, the code must:

- 1. Already include the technical PACS workstation direct PE input;
- 2. Typically require the use of a professional PACS workstation;
- 3. Not be an "add on" code; and
- 4. Have diagnostic radiology as the dominant specialty provider for the service.

Putting aside the dominant specialty provider requirement, which we address below, many of SVU's vascular ultrasound codes¹⁰ satisfy the criteria set forth above.¹¹ In declining to apply the new PACS input to vascular ultrasound codes and some other services, CMS did not provide any explanation or rationale for its belief that such services do not use PACS workstations. Further, we are deeply concerned that CMS' rationale is not applicable to vascular ultrasound.

The vascular ultrasound codes are, at their core, diagnostic imaging services. As noted above, vascular ultrasound is a critical diagnostic imaging tool that uses sound waves to obtain images of internal anatomic structures, offering a highly sensitive, non-invasive, and low-cost means of examining internal vessels. Following the industry's transition from film to digital imaging, use of **both** the technical and professional PACS workstations became typical for vascular ultrasound services, like other diagnostic imaging services. Indeed, both CMS and the American Medical Association Relative Value System Update Committee ("AMA RUC") recognized vascular ultrasound's transition from film to digital imaging in 2015 by replacing the historic film direct PE inputs with the technical PACS workstation direct PE input in the vascular ultrasound codes. Moreover, in an effort to assist the Agency with valuing the technical PACS workstation input, SVU submitted its members' invoices for technical PACS workstations, reflective of the workstation's widespread use in furnishing vascular ultrasound services.

The Agency's express recognition of the utilization of PACS workstations in furnishing vascular ultrasound services makes CMS' belief, that, just two years later, such imaging services may not actually use PACS workstations for imaging purposes, difficult to understand. Moreover, the Agency's decision not to add the professional PACS workstation to vascular ultrasound codes that meet the Agency's own

¹⁰ The following vascular ultrasound codes represent 75% of the volume of services performed by SVU's members: 93880, 93922, 93923, 93925, 93926, 93970, 93971, 93975, 93976, and 93978. Diagnostic radiology is the dominant specialty provider for the majority of these codes (93880, 93926, 93970, 93971, 93975, 93976).

¹¹ Based on the most recent annual utilization data available from CMS, some vascular ultrasound codes have different specialties, including cardiology, vascular surgery, and neurology, as the dominant provider, with diagnostic radiology in the top five highest volume providers for those codes.

criteria set forth above seems arbitrary. It also inaccurately reflects the resources required to furnish such services and, as a result, disrupts the relativity of the PFS.

In addition, although the majority of SVU's highest utilization codes¹² satisfy CMS' requirements for the addition of the professional PACS workstation input, including the requirement that diagnostic radiology be the dominant specialty provider for the relevant service, SVU is deeply concerned that, from a policy perspective, CMS' dominant specialty provider requirement seems arbitrary.

As an initial matter, CMS' stated premise in the CY 2017 Final Rule for requiring diagnostic radiology to be the dominant specialty provider of a service in order for that code to receive the new professional PACS workstation input is that "the PACS professional workstation is only typically used by radiologists." The Agency, however, does not provide any rationale in support of this conclusion. Further, as a factual matter, we are concerned that CMS' understanding of the typical use of a PACS workstation is incorrect, at least with respect to vascular ultrasound. As noted above, to furnish vascular ultrasound services following the transition from film to digital imaging, both a technical and a professional PACS workstation are required. This is true regardless of the provider performing the service, which, as reflected in the specialty utilization data for SVU's vascular ultrasound codes, may also include cardiologists, neurologists, and vascular surgeons.

Indeed, in a recent survey conducted by SVU, providers overwhelmingly reported that vascular ultrasound services require the use of both a technical PACS workstation and a professional PACS workstation. Specifically, the 2017 SVU survey, which had nearly 250 responses from multiple specialties and sites of services, ¹³ demonstrated that 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 76707 (formerly G0389) were typically furnished using both the technical and professional PACS workstations. ¹⁴

Accordingly, to limit the inclusion of the professional PACS workstation input to those codes in which the utilization data for a given year identifies diagnostic radiology as the dominant provider specialty (rather than the second or third most dominant provider specialty) arbitrarily introduces the potential for unnecessary annual fluctuations with respect to inputs assigned to particular codes and does not consistently reflect the actual resource costs associated with furnishing the underlying services, ultimately disturbing the relativity of the PFS.

¹² The following vascular ultrasound codes represent 75% of the volume of services performed by SVU's members: 93880, 93922, 93923, 93925, 93926, 93970, 93971, 93975, 93976, and 93978. Diagnostic radiology is the dominant specialty provider for the majority of these codes (93880, 93926, 93970, 93971, 93975, 93976).

¹³ Respondents were from a diverse geographic background with 13.31% being from rural areas, 37.1% identifying as suburban, and 49.6% selecting urban as their place of service. The primary practice type that the survey respondents selected was also significantly wide-ranging: (1) hospital outpatient department –31.45%; (2) independent diagnostic testing facilities –10.89%; (3) solo physician practices—2.82%; (4) single specialty physician—22.18%; (5) multiple specialty physician—14.93%; (6) ambulatory surgical center—1.21%; and (7) other—15.53%. Finally, the primary practice specialty affiliation of the respondents was similarly diverse: (1) vascular surgery—58.37%; (2) vascular medicine—6.94%; (3) cardiology—15.51%; (4) diagnostic radiology—9.8%; (5) family and internal medicine—1.23%; and (6) other (including neurology)—8.16%.

¹⁴ Indeed, for all vascular ultrasound codes surveyed, <u>more than 80% of respondents</u> reported that both technical and processional PACS workstations were required to furnish the services.

III. Variable Maintenance Factor Assumption

SVU applauds CMS' willingness to continue to "investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items," consistent with the Agency's recognition in prior rulemaking cycles that "the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment." In addition, we urge CMS' to make the "maintenance cost" factor in the "equipment cost per minute" calculation variable, similar to other assumptions in the calculation.

The maintenance cost rate included in the calculation is currently standard across all equipment items. This standard rate assumption, however, fails to appreciate the significant costs associated with the maintenance of highly technical and particularly complex equipment items, such as the PACS. Despite receiving "extensive comments" in support of making the maintenance cost factor variable, CMS did not finalize this proposal for CY 2016. While we appreciate CMS' commitment "to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items," we continue to believe that CMS should not persist in an inaccurate approach, while it collects additional data, where it has data for particular services, as it does for vascular ultrasound.

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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,

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¹⁵ 80 Fed. Reg. at 70896.

¹⁶ 80 Fed. Reg. at 70897.