SOCIETY FOR VASCULAR ULTRASOUND

January 27, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1600-FC: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

Dear Administrator Tavenner:

The Society for Vascular Ultrasound ("SVU") thanks the Centers for Medicare and Medicaid Services ("CMS") for this opportunity to comment on revisions to payment policies under the Physician Fee Schedule ("PFS") for calendar year ("CY") 2014 (the "Final Rule with Comment").[1] SVU is a professional society comprised of over 4,600 vascular technologists, sonographers, nurses, and physicians. SVU members provide a variety of high-quality vascular ultrasound services[2] to Medicare beneficiaries. Although there are aspects of the Final Rule with Comment we support, unfortunately, there is at least one component of the Final Rule with Comment, specifically, the finalized "refinements" to 93880's direct practice expense ("PE") recommendations,[3] about which we are deeply concerned. We believe that this component of the Final Rule with Comment fails to comply with the notice and comment requirements of the Administrative Procedure Act ("APA").[4] Further, it will continue to perpetuate inadequate Medicare reimbursement for these services, which inevitably results in Medicare beneficiaries' inability to access high quality Medicare services and providers and increases utilization of more expensive alternative diagnostic procedures, many of which involve radiation exposure.

[1] 78 Fed. Reg. 74,230 (Dec. 10, 2013).
[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, and G0365.
[3] 78 Fed. Reg. at 74,373.
[4] 5 U.S.C. § 553(b)–(c).

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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 it 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 Final Rule with Comment from the perspective of vascular ultrasound.

As noted above, SVU is deeply troubled with CMS' proposal to "refine" and finalize the minutes associated with 93880's four direct PE inputs[5] because: (1) the refined finalization does not comply with the notice and comment requirements of the APA and (2) CMS' significant "refinements" are not justified based on how the 93880 service is typically provided. We see no evidence supporting CMS' decision here. Indeed, none is cited in the Final Rule with Comment.

First, the APA requires that CMS publish any proposed refinements to 93880's direct PE inputs, as well as any other components that affect 93880's and other health care services' reimbursement rates, in the Federal Register with an opportunity for public comment.[6] The APA also requires that CMS consider public comments and provide a response to such comments, along with a rationale for the final CMS rule when the final rule is published in the Federal Register.[7]

Second, the APA bars any agency rulemaking that is "arbitrary and capricious,"[8] in other words where the agency has failed to "examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made."[9]

Unfortunately, CMS failed to satisfy both of these two fundamental APA requirements with respect to 93880's refined direct PE inputs. Specifically, the proposed rule for the 2014 CY PFS was absolutely silent about the possibility of refining 93880's relative value units ("RVUs"), let alone its four direct PE inputs.[10] Thus, SVU and other interested stakeholders had no idea that CMS was contemplating further refinements to 93880's direct PE inputs, as initially recommended by the American Medical Association/Specialty Society Relative Value Update Committee ("AMA RUC").

Furthermore, when CMS did communicate its decision to further "refine" 93880's direct PE inputs from the AMA RUC's recommendations, it did so in the Final Rule with

[5] 78 Fed. Reg. at 74,373.
[6] 5 U.S.C. § 553(b)–(c).
[7] *Id.* § 553(c).
[8] 5 U.S.C. § 706(2)(A).
[9] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).
[10] *See generally* 78 Fed. Reg. 43,282 (July 19, 2013).

Comment, implementing its policy without first giving any opportunity for comment.[11] Its policy was, in fact, expressed as a final decision that was effective January 1, 2014.[12]

As a result, the refinements to 93880's direct PE inputs are in violation of the APA and should be immediately delayed until CMS has time to consider and respond to public comments, as well as modify, as necessary, any refinements to 93880's direct PE inputs. This delay is further supported by CMS' own proposal to not refine the current work components of 93880, and other codes, until the AMA RUC and other interested stakeholders have an opportunity to comment.[13] Thus, there is both a legal reason to delay the refinements to 93880's direct PE inputs, and also a very strong administrative simplification reason to delay the refinements to 93880's direct PE inputs.

While SVU believes that, legally, CMS must delay the refinements to 93880's direct PE inputs until the APA procedural notice and comment requirements are satisfied, delay is also required because CMS' change to 93880's direct PE inputs, without any justification, contravenes the APA's prohibition on "arbitrary and capricious" rulemaking.[14] The procedure time assumptions CMS has made for the purposes of determining the direct PE inputs for the "room, ultrasound, vascular" equipment package (EL016) ("the Vascular Ultrasound Room") are incorrect and do not reflect how 93880 is routinely furnished to Medicare beneficiaries. Specifically, at CMS' request, the AMA RUC recommended that sixty-eight (68) minutes be assigned to the Vascular Ultrasound Room with respect to 93880, and CMS has, based on the Final Rule with Comment itself, absolutely no data that suggests otherwise.[15] Nevertheless, without any such evidence, CMS has enacted a radically different policy. The only explanation CMS provided for this "refinement" was "[r]efined equipment time to conform to established policies for technical equipment."[16] It failed to supply any data supporting its position.

In speaking further with CMS personnel, it is our understanding that the additional seventeen (17) minute reduction taken by the agency stems from CMS' assumption that certain pre-service services, namely greeting and gowning the patient, obtaining patient history, and acquiring the patient's vital signs, are not performed in the Vascular Ultrasound Room, and, thus, the seventeen (17) minutes associated with these services can be deducted. Notably, CMS did not cite any factual support for this assumption, and did not articulate any connection between the relevant data the APA requires the agency to consider and the conclusion it reached. Stakeholders were also not provided with any previous notice and opportunity to comment, and thus, were precluded from being able to submit supportive or contradictory evidence of CMS' pre-service presumption. This kind of inherently flawed process is exactly what the APA prohibits.

[11] 78 Fed. Reg. at 74,343.
[12] *See id.* at 74,230.
[13] *Id.* at 74,343.
[14] 5 U.S.C. § 706(2)(A).
[15] 78 Fed. Reg. at 74,373.
[16] *Id.*

In order to ascertain whether there is factual support for CMS' reduction in 93880's direct PE inputs for the Vascular Ultrasound Room, SVU surveyed its members. Despite the extremely brief time period available to conduct such a survey, and the many distractions of the holiday season that occurred throughout the survey window, well over 500 healthcare providers submitted a response, which seems to be a vastly superior data set than CMS used (indeed, the Final Rule with Comment suggests that there was no such data). These providers practice at institutions across the full spectrum of SVU's membership, including hospitals, inpatient and outpatient departments, clinics, independent diagnostic testing facilities, and a variety of physician practices (*e.g.*, cardiology, internal medicine, neurology, etc.).

In short, SVU's survey results demonstrated that CMS' presumption that certain pre-service services are not performed in the Vascular Ultrasound Room is blatantly incorrect. Almost every single provider reported that part of the 93880 services they conduct in the Vascular Ultrasound Room include obtaining the patient's history and verifying that the procedure about to be performed is the correct one.[17] In addition, nearly all providers when performing 93880 greet and gown the patient in the Vascular Ultrasound Room.[18] Finally, the vast majority of the 93880 procedures involve a provider acquiring the patient's vital signs in the Vascular Ultrasound Room.[19] These survey results emphatically demonstrate that CMS' presumption was incorrect and that the AMA RUC's recommendation of sixty-eight (68) minutes accurately reflects the amount of time that 93880 services are performed in the Vascular Ultrasound Room. As such, should CMS choose to not delay the 93880 refinements, we strongly urge CMS to adopt the AMA RUC's recommendation and assign sixty-eight (68) minutes to the Vascular Ultrasound Room for 93880.

Moreover, the arbitrary and capricious nature of CMS' pre-service presumption is further illustrated by the change in direct PE inputs for 93882, which experienced a nineteen (19) minute decrease in the time assigned to the Vascular Ultrasound Room, despite an analysis by the AMA RUC suggesting that a four (4) minute decrease was appropriate.[20] As with the "refinement" of 93880's direct PE inputs, the only justification CMS provided for this change was, "[r]efined equipment time to conform to established policies for technical equipment."[21] CMS did not explain why it subtracted fifteen (15) minutes more for the service time in the Vascular Ultrasound Room than the

[17] Specifically, 96.0 percent of the survey respondents indicated that this pre-service is performed in the Vascular Ultrasound Room.
[18] Namely, 88.0 percent of the survey respondents indicated that this pre-service is performed in the Vascular Ultrasound Room.
[19] Notably, 80.5 percent of the survey respondents indicated that this pre-service is performed in the Vascular Ultrasound Room.
[20] *Compare* 78 Fed. Reg. at 74,373 *with* CY 2013 PFS Direct PE Inputs (Nov. 16, 2011), *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1590-FC.html?DLPage=1&DLSort=3&DLSortDir=descending.
[21] 78 Fed. Reg. at 74,373.

AMA RUC's data indicated, just as it did not explain why it was subtracting an additional seventeen (17) minutes from the AMA RUC's estimate for 93880.

Based on the forgoing, SVU strongly believes that for various legal reasons discussed above, CMS must delay the refinements to 93880's direct PE inputs. SVU recommends that once CMS has the AMA RUC's recommendations for all RVU components for 93880 and other codes, then CMS should consider and propose such refinements, if any, during an upcoming rulemaking process. Should CMS decide to not delay 93880's refinements, then we strongly urge CMS to adopt the AMA RUC's recommendation of sixty-eight (68) minutes assigned to the Vascular Ultrasound Room for 93880, as this amount of time is the most accurate reflection of how the 93880 service is currently performed and will ensure the most appropriate and fair reimbursement rate for 93880. This will in turn help to ensure that Medicare beneficiaries have appropriate and meaningful access to high-quality vascular ultrasound services.

SVU would be happy to provide additional information on any or all of the aforementioned issues. We look forward to continuing to work with CMS to improve the health of Medicare beneficiaries, and we thank you in advance for your thoughtful consideration of our comments.

Respectfully submitted,

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