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

RE: CMS-1503-P: Medicare Program; Payment Policies Under
the Physician Fee Schedule and Other Revisions to Part B
for CY 2011; Proposed Rule

Dear Administrator Berwick:

The Society for Vascular Ultrasound ("SVU") thanks the Centers for Medicare and Medicaid Services ("CMS") for this opportunity to comment on the proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2011 (the "Proposed Rule").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 to Medicare beneficiaries, but primarily the procedures described by Current Procedural Terminology ("CPT") codes 92922-93990.

Ultrasound is a critical 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. As a result, both primary care and specialty physicians rely on ultrasound as the primary, and often definitive, diagnostic tool in many instances. Increasingly, physicians employ ultrasound testing as the sole examination prior to surgical intervention, not only saving Medicare dollars, but also reducing the risks involved with other invasive modalities. With this in mind, SVU offers these comments to the Proposed Rule from the perspective of vascular ultrasound.

¹ 75 Fed. Reg. 40040 (July 13, 2010).

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

- **Removal of Barriers to Preventive Services & Coverage of Annual Wellness Visits:** SVU supports the removal of cost-sharing obligations from certain preventive services, including, but not limited to ultrasound screening for abdominal aortic aneurysm ("AAA"). Similarly, SVU applauds CMS for expanding Medicare coverage to include annual wellness visits that creates an individualized preventive plan.
- **Expansion of the Multiple Procedure Payment Reduction ("MPPR") Policy:** SVU is highly concerned about CMS' proposed expansion of the MPPR policy to all multiple imaging services' codes that are furnished to the same patient in the same session, regardless of the imaging modality, and not limited to contiguous body areas.
- **Physician Quality Reporting Initiative ("PQRI"):** SVU commends CMS for its proposal to expand the PQRI program criteria, provide increased incentives for physicians to participate in this important, voluntary program, and recommends that CMS adopt a PQRI measure for AAA ultrasound screening.
- **Improvements to the Physician Resource Use Measurement & Reporting Program ("RUR") and Future Implementation of Payment Modifier under the Physician Fee Schedule:** SVU thanks CMS for its careful phase-in implementation of the RUR program, and requests that CMS adopt a policy that if a provider, subject to the RUR program, does not receive a confidential feedback report prior to the implementation of the payment modifier, then the provider is not subject to the payment modifier until they receive and have meaningful time to implement the feedback CMS provided in the confidential report.

These comments are discussed at greater length below. We thank you in advance for your consideration of SVU's comments.

I. Removal of Barriers to Preventive Services & Annual Wellness Visits

As noted in the Proposed Rule, section 4104 of the Patient Protection and Affordable Care Act ("ACA")² eliminated Medicare beneficiaries' cost-sharing for the

² Pub. L. 111-148. Note for consistency with the Proposed Rule, we will refer to the PPACA and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, collectively as the Affordable Care Act ("ACA").

initial preventive physical examination, the annual wellness visit, and certain preventive services.³ In order to implement this new statutory requirement, CMS proposes to include ultrasound screening for AAA as one of the preventive services for which Medicare beneficiaries will not be subject to any cost-sharing requirement.⁴

The focus of SVU is detection and management of vascular diseases, so increased focus on prevention and wellness are crucial to detection and management of vascular disease and its complications. Accordingly, SVU supports the ACA and CMS for removing certain preventive services' cost-sharing requirements, which historically prohibited Medicare beneficiaries from seeking crucial preventive services and, therefore, likely cost the Medicare program significantly more than if the preventive services had or had not been performed. Specifically, SVU believes the expansion of the Medicare Part B program to include the initial and subsequent wellness exams that provide personalized prevention plans for the vulnerable Medicare beneficiary population will not only enhance Medicare beneficiaries' lives, but also result in savings to the Medicare program.

Furthermore, SVU applauds CMS from recognizing AAA ultrasound screening as one of the specific preventive services for which Medicare should cover and no longer subject to cost-sharing obligations. It is estimated that over one million Americans have AAA and at least 95 percent of these can be successfully treated if detected prior to rupture. However, because AAA is almost always asymptomatic, the problem largely goes undetected and untreated, leading to needless loss of life. SVU believes that this proposal will ensure that physicians and other appropriate providers consider AAA ultrasound screening when developing each Medicare beneficiary's personalized prevention plan and reduce the percentage of Medicare individuals that need, but do not receive, appropriate and necessary treatment for asymptomatic AAA. This will not only guard against needless loss of life, but also help guarantee that Medicare beneficiaries are able to access preventive services without having to specifically inquire about them or be forced to make difficult financial choices between competing life-necessities in these difficult economic times.

II. Expansion of the Multiple Procedure Payment Reduction ("MPPR") Policy

SVU is highly concerned about CMS' proposed expansion of the MPPR policy. Currently, this policy targets five imaging modalities, including ultrasound, that are associated with eleven CPT code families and involve imaging of contiguous body areas.⁵ Under the current MPPR policy, the technical component ("TC") of the highest reimbursed procedure is paid in full, but each additional procedure performed during the same session on the same patient's contiguous body part, using the same imaging modality, has its TC reimbursement reduced by 25%.⁶

³ Pub. L. 111-148, § 4104.

⁴ 75 Fed. Reg. at 40129.

⁵ 75 Fed. Reg. at 40073.

⁶ 75 Fed. Reg. at 40074.

Section 3135 of the ACA has since modified the MPPR policy by increasing the TC reimbursement reduction percentage from 25% to 50%, which effectively further reduces subsequent imaging procedures' reimbursement.⁷ Even with this new cut in imaging services' reimbursement, CMS is now proposing to expand the MPPR policy to all imaging service codes that are furnished to the same patient in the same session, no matter what imaging modality is used and regardless of what part of the Medicare beneficiary's body is being imaged and evaluated.⁸ This is an area where ultrasound differs greatly from other imaging modalities, as ultrasound is an imaging modality that is primarily used to make appropriate clinical decisions about how best to treat the patient in the most cost-effective manner by effectively ruling out the need for further advanced diagnostic imaging procedures. In addition, computed tomography ("CT"), magnetic resonance imaging ("MRI"), and X-ray can be expanded to include multiple body parts with a simple change in settings of the instrumentation. However, with ultrasound, imaging multiple body parts is often crucial to evaluate the impact of a narrow vessel on the organs supplied by that vessel. If a vessel is critically narrowed in the abdomen, it will impact flow to the lower half of the body, so that the entire course of that vessel must be imaged from the abdomen to the feet. Although this would technically constitute multiple body parts, and thus be subject to the reduced reimbursement under the MPPR policy, it would be malpractice to provide an incomplete evaluation.

For example, when evaluating the carotid artery, to determine if the artery has narrowed diminishing blood flow to the brain, if such a narrowing is documented during an ultrasound procedure there is a risk that the patient might experience a stroke and, thus, there is a potential need for intervention. Consequently, it may be necessary to perform an assessment of blood flow both to and within the brain, to see the impact of the carotid artery's narrowing on the maintenance of blood flow to the brain to better assess the patient's risk of having a stroke. These ultrasound studies are critical to complete a full evaluation and potentially prevent a stroke, but would likely be subject to reduced reimbursement under the MPPR policy, as they are likely going to be performed on the same patient in the same day.

However, the efficiencies CMS presumes will occur and uses as its rationale for the reduced reimbursement under MPPR, will likely not occur because these two ultrasound procedures will not likely be performed right after one another. Instead, it is more likely that the ultrasound study will be performed first to evaluate if the carotid artery has narrowed. Then, if a narrowing is observed, this will have to be communicated to the physician, who will then need to determine the course of treatment and whether a blood flow ultrasound study is required. If a blood flow study is requested, the patient has likely left the exam room and the sonographer has moved on to another patient. Accordingly, even though the patient received an ultrasound procedure earlier that day, all the prep work associated with performing an ultrasound procedure will have to be

⁷ *Id.*

⁸ *Id.*

repeated and no efficiencies will be achieved. Yet, under CMS' proposed expansion of its MPPR policy, reimbursement for these studies will be reduced.

Interestingly, CMS claims that its proposed expansion of the MPPR policy is a "first step" in implementing Section 3134 of the ACA, which directs CMS to identify, review, and make any appropriate adjustments to potentially misvalued codes.⁹ While SVU understands that CMS is responsible for identifying, reviewing and adjusting potentially misvalued codes, it is not readily apparent how an expansion of the MPPR policy to additional imaging services fits within the authority granted by Section 3134 of the ACA. Furthermore, the fact that CMS only cited a July 2009 Government Accountability Office ("GAO") report¹⁰ for support of this proposal, and failed to acknowledge other sources, as well as other CMS proposals, only increases the confusion surrounding the proposed expansion of the MPPR policy.

First, the cited GAO report states that the code identification, review, and adjustment process takes specialty societies approximately fourteen months and is incredibly resource intensive.¹¹ This is consistent with the time period it took the GAO to complete its own systematic review for this report, which occurred from May 2008 through July 2009, approximately fourteen months.¹² Considering it has only been thirteen months since the publication of the 2009 GAO report, four months since the passage of the ACA, and the fact that CMS now has numerous new obligations under the ACA, we find it highly unlikely that CMS has the necessary data or has had the time and resources to conduct a thorough and systematic review all of these imaging codes subject to the proposed expanded MPPR policy. Instead, it seems that CMS has made an unsupported, blanket reduction to imaging codes' reimbursement.

Second, when discussing the current limitations and possible options for expanding the MPPR policy, the GAO report specifically recommends that CMS focus on a broad range of services, as the MPPR does not apply to non-surgical or non-imaging services and, therefore, fails to recognize efficiencies achieved when certain non-surgical, non-imaging procedures are performed together.¹³ Accordingly, the GAO report concludes that CMS should systematically review a broad range of services commonly furnished together and update the MPPR policy to capture efficiencies appropriately identified.¹⁴ Thus, it seems that CMS is citing a GAO report for support of its proposed expanded MPPR policy to all imaging services and then ignores the GAO's recommendations therein, namely that CMS should focus on other non-surgical, non-imaging codes when considering expansion of the MPPR policy.

⁹ *Id.*

¹⁰ GAO, Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together, GAO-09-647 (July 2009); 75 Fed. Reg. at 40074.

¹¹ GAO, Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together, GAO-09-647, p. 5 & 17.

¹² *Id.* at 4.

¹³ *Id.* at 7 & 12.

¹⁴ *Id.* at 15.

In addition, the GAO report was published prior to the passage of the ACA, which modified the MPPR policy, resulting in additional reimbursement reductions for imaging services that are subject to the MPPR. Thus, the report's recommendations concerning imaging services are no longer valid, because they fail to take into account the ACA's change to the MPPR policy and the resulting additional reductions to imaging services' reimbursement rates.

As a result, SVU strongly urges CMS to withdraw its proposed MPPR expansion policy, as it is unsupported and appears to not follow the specific requirements mandated by the ACA in order to exercise the authority granted therein. Furthermore, the ACA's reduction in imaging services' reimbursement, through the MPPR policy modification, alone will have a significant impact on Medicare beneficiaries ability to access necessary imaging services. Thus, if CMS implements additional cuts to already reduced imaging services' reimbursement by finalizing its proposed expansion of the MPPR policy, the effect on Medicare beneficiaries' access to imaging services could be catastrophic. Accordingly, SVU implores CMS to withdraw its proposal to expand the MPPR policy, take the necessary time to appropriately identify, evaluate and make supported reimbursement adjustment proposals as the ACA directs, and not combine two significant cuts to imaging services' reimbursement at the same time.

III. Physician Quality Reporting Initiative ("PQRI")

We thank CMS for its continued efforts to ensure and improve the quality and safety of physician services through PQRI and support CMS' proposal to expand and make the voluntary reporting program more accessible and attractive to physicians by reducing the reporting sample requirements for claims-based reporting of individual measures from 80% to 50%. SVU also applauds CMS for proposing to maintain a vast majority of the 2010 PQRI measures, including measure 172: Hemodialysis Vascular Access Decision-Making by Surgeon To Maximize Placement of Autogenous Arterial Venous and measure 201: Ischemic Vascular Disease (IVD): Blood Pressure Management Control.

SVU has worked to develop quality measures for technologists and physicians since 1983, by helping to develop nationally recognized certification exams for vascular technologists, physicians who interpret vascular ultrasound exams and facilities providing vascular ultrasound services. These efforts demonstrate our deep commitment to quality, and the PQRI criteria very nicely reflect additional quality measures to improve efficiency and quality of care.

Accordingly, SVU appreciates that when CMS considers new measures to include in the program, the Social Security Act ("the Act") requires that the measures be endorsed by the National Quality Forum ("NQF").¹⁵ However, section 1848(k)(C)(ii) of

¹⁵ The Social Security Act, § 1848(k)(2)(C)(ii); 75 Fed. Reg. at 40183.

the Act allows CMS to adopt a non-endorsed measure for a specified area or medical topic if there is no feasible or practical measure that has been endorsed by NQF, so long as due consideration is given to NQF endorsed measures.¹⁶ Accordingly, SVU agrees with CMS' proposal to add twenty new PQRI measures that have been endorsed by NQF,¹⁷ as well as CMS' proposal to exercise its exception authority for certain non-NQF endorsed measures related to audiologists.¹⁸ Similarly, SVU urges CMS to also consider exercising its exception authority in adopting a measure for AAA ultrasound screening, as there does not appear to be a feasible or practical NQF endorsed measure for this specified area. By adopting the AAA ultrasound screening measure as a PQRI measure, CMS will have increased ability to monitor whether beneficiaries are actually being provided access and utilizing this important preventive service, resulting in increased quality of care and health outcomes for Medicare beneficiaries, as well as savings to the Medicare program.

SVU believes that the proposed expansion of the PQRI criteria combined with the decreased threshold for physicians to become eligible for the incentive payments will likely translate into increased participation in the voluntary PQRI program. Accordingly, any increase in physician participation in the PQRI program will likely lead to greater quality services provided by physicians to Medicare beneficiaries, which will in turn lead to greater Medicare beneficiary satisfaction and potentially lower costs to the Medicare program. SVU supports this, and any proposal, which effectively incentivizes physicians to report and subsequently provide greater quality services to the Medicare population.

IV. Improvements to the Physician Resource Use Measurement & Reporting Program ("RUR") and Future Implementation of Payment Modifier under the Physician Fee Schedule

SVU thanks CMS for the cautious and deliberate, phase-in approach it has taken with regards to implementing the RUR. SVU also applauds CMS for requesting stakeholder input on how best to continue RUR's implementation and modification, especially since the ACA requires that the Secretary apply a separate budget neutral payment modifier to the physician fee schedule payment formula beginning on January 1, 2015.¹⁹

While SVU strongly supports CMS' proposal to add quality measures to the already reported cost measures for physicians under RUR,²⁰ SVU is concerned of the potential misuse of cost in determining quality care. Accordingly, SVU urges CMS to ensure that both cost and quality of care measures are evaluated together, as opposed to

¹⁶ *Id.*

¹⁷ 75 Fed. Reg. at 40186-40198.

¹⁸ 75 Fed. Reg. at 40190.

¹⁹ 75 Fed. Reg. at 40114.

²⁰ *Id.*

using one measure to determine the other when comparing physicians to their peers and, ultimately, making reimbursement decisions based on these comparisons.

Furthermore, SVU applauds CMS' desire to ensure that every physician receives a confidential RUR report with suggestions prior to the implementation of the RUR payment modifier.²¹ However, SVU urges CMS to adopt a policy that if a physician or relevant provider does not receive a confidential RUR report with the appropriate feedback, prior to the implementation of the RUR payment modifier, then the physician or provider will not be subject to the payment modifier policy until after the physician or provider receives his or her confidential report and sufficient time has passed to allow the physician or provider to appropriately modify his or her practices.

With respect to the specific RUR measures that CMS is requesting stakeholder input on, SVU provides the following comments for CMS' consideration:

- **Risk Adjustment:**²² SVU believes that socioeconomic status should be included in the Hierarchal Condition Categories ("HCC"), even if the previous regression analysis indicated that these socioeconomic factors did little to improve the fit of the model, because socioeconomic status, in reality, will likely have a significant and predictable effect on which Medicare beneficiaries are able to comply with their treatment or preventative plans, whether from an educational, monetary, and/or access standpoint.
- **Attribution:**²³ SVU believes that the current multiple proportional and plurality minimum models may unevenly and unfairly attribute Medicare beneficiaries' costs to certain specialties over other specialties. While SVU understands that no model will perfectly and accurately attribute Medicare beneficiaries' costs to the appropriate provider in all circumstances, SVU believes that the two other attribution models proposed by CMS, namely attributing the entire cost of a surgical episode to the performing surgeon and the multiple even models will have greater success in evenly and fairly attributing Medicare beneficiaries' costs to the appropriate provider in more situations than the multiple proportional and plurality minimum models currently used. Thus, SVU urges CMS to adopt the multiple even model and in surgical cases, attribute the entire cost of the surgical episode to the performing surgeon.
- **Cost and Quality Measures and Compositing Methods:**²⁴ In developing the cost and quality measures to determine a composite score, SVU urges CMS to ensure that compliance with preventative health service

²¹ *Id.*

²² 75 Fed. Reg. at 40115

²³ 75 Fed. Reg. at 40115-40116.

²⁴ 75 Fed. Reg. at 40116.

measurements is taken into account when developing the composite score methodology. This will help ensure that compliant physicians that are improving Medicare beneficiaries lives, while at the same time saving the Medicare program money by recommending or providing appropriate preventive health services, are properly awarded for their exceptional practice of medicine.

V. CONCLUSION

We thank you in advance for your consideration of our comments to the Proposed Rule regarding payment for removal of barriers to preventative services, the proposed expansion of the MPPR policy, the PQRI program, and the RUR program provisions. 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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