September 24, 2004

VIA ELECTRONIC MAIL

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W
Washington, D.C. 20201

RE: <u>CMS-1429-P</u>

Dear Administrator McClellan:

On behalf of the Society for Vascular Ultrasound (SVU), we thank you for the opportunity to comment on the August 5, 2004 Notice of Proposed Rulemaking ("NPRM") released by the Centers for Medicare and Medicaid Services ("CMS") regarding the Medicare Physician Fee Schedule for 2005. These remarks relate solely to the treatment of technical component ultrasound services under the fee schedule.

The SVU is a professional society comprising over 3,500 members who consist of registered vascular technologists, nurses as well as nearly 1,000 physicians. SVU members provide high quality vascular ultrasound services to Medicare beneficiaries. Our members deliver the procedures described by CPT codes 92922-93990.

A. Summary of Our Comments

We thank CMS for adopting the practice expense refinements that we proposed with respect to the ultrasound machines used to provide our services. This refinement is most welcome and ensures a much more accurate payment for our services. However, we note that CMS has not yet adopted the additional refinements that we suggested for the other ancillary equipment present in a vascular ultrasound room. These additional expenses should be reflected in CMS's practice expense calculation for vascular ultrasound services. We ask that these additional refinements be made and made effective for January 1, 2005.

We applaud CMS for proposing a new code to appropriately reimburse providers for vein mapping in connection with hemodialysis access. Because of the practice patterns that exist and the clinical realities that apply, we encourage CMS to permit payment for the interpretation of these services to providers other than "the operating surgeon." We make certain suggestions regarding refinements to the proposed code which we believe will more accurately reflect the nature of the service to be provided.

We enthusiastically support the references to the need for appropriate quality standards being put in place in connection with the vein mapping procedure. In this regard, we strongly encourage CMS to adopt a requirement that the service only be payable where the technical component service is provided by an

individual who is credentialed by an appropriate national credentialing body in vascular technology or by a laboratory that has been accredited by an appropriate national accreditation body. We note that the clear majority of Medicare carrier jurisdictions require this standard to be met in connection with all other vascular ultrasound services. Because these services are so operator-dependent, the services simply are not reasonable and necessary in the absence of credentialing or accreditation.

B. Background

Ultrasound is a critical diagnostic imaging modality that uses sound waves to obtain images of the interior of the body. Because ultrasound offers a highly sensitive, non-invasive, low-cost means of looking into the body of a patient to examine structures, such as organs, vessels or a fetus, physicians from numerous specialties and primary care rely on ultrasound as their primary, and often definitive, diagnostic tool in many instances. Increasingly, physicians employ ultrasound testing as the sole examination prior to surgical intervention saving not only Medicare dollars but reducing the risks involved in other invasive modalities.

C. Practice Expense Input Refinements

SVU is grateful to CMS for the significant effort undertaken by the Agency to make certain refinements to the practice expense inputs that apply to vascular ultrasound services. CMS' commitment to ensuring fair and appropriate reimbursement is commendable and much appreciated. We commend CMS for its inclusion of new practice expense inputs for the family of noninvasive vascular codes (CPT codes 92922-93990). By recognizing the appropriate cost of ultrasound machines, CMS has addressed a major issue for our services and other ultrasound services that, in the past, resulted in services being undervalued from a PERVU perspective.

We note, however, that CMS has not, as yet, incorporated our requested refinements for a vascular ultrasound room that would capture the significant other equipment costs associated with vascular ultrasound services that are in addition to the expense of the ultrasound room itself. These additional expenses are incurred solely for vascular ultrasound services, and not for other ultrasound services. We would be most grateful if CMS could adopt these additional refinements and make them effective for January 1, 2005.

D. Vein Mapping for Hemodialysis

SVU wishes to commend CMS for its proposal regarding vein mapping before hemodialysis access surgery. The CMS proposal focuses on the creation of a new G-code (G0XX3: Venous mapping for hemodialysis access placement. We strongly support CMS's proposal, though we offer several suggestions regarding how it should be refined.

First, we wish to note that we strongly agree with your comments that "autogenous grafts have longer patency rates, a lower incidence of infection and greater durability than prosthetic grafts. Use of autogenous grafts can also result in a decrease in hospitalizations and morbidity related to vascular access complications." This has been well documented in the literature with substantial evidence that pre-operative ultrasound mapping of the veins and arteries of the arms does, in fact, provide a positive impact on outcomes. We also agree that a new code may allow CMS to track use of venous mapping for quality improvement purposes. We do, however, have some concerns over the implementation of the procedure, as currently proposed.

For example, we are concerned that restricting the use of the newly created G code by requiring the "service to be performed by operating surgeon……" does not appear to reflect current clinical practice. In this regard, we note the following:

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> In practice the mapping is often performed prior to referral to the vascular surgeon. CMS and others have sponsored an initiative called Fistula First. In step three of the Fistula First Change Package, the statement is made that the "[n]ephrologist refers for vessel mapping where feasible, ideally prior to surgery referral". Fortunately, the technical component of these services will nearly always be performed by a vascular technologist who specializes in the performance of this procedure, regardless of who makes the referral.

The process of scheduling vascular mapping is such that the operating surgeon may be unavailable to perform even the professional component of the mapping. Most vascular laboratories have multiple physicians doing the professional interpretation on a regularly scheduled basis. The patient is usually given a choice of times to have the vascular mapping performed, and that may be done at a time when the operating surgeon is not assigned or available to perform the interpretation. An appropriately qualified non-operating physician can safely interpret vascular mapping. As we indicate more fully below, the most appropriate means to ensure that the services that are provided are reasonable and necessary are to require that the services be performed by accredited laboratories or credentialed technologists following the appropriate guidelines. In any event, we would suggest that the proposed "operating surgeon" requirement be abandoned.

We also believe that the proposed coding itself should be modified. The proposed code's descriptor, as written, is identical to code 93971, *Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study.* This descriptor does not accurately reflect the procedure as it is now being performed.

Most existing vascular laboratory protocols include a Doppler evaluation of the arterial system to assure adequacy of arterial inflow. This is a critical part of the examination, as arterial inflow problems are routinely encountered in these patients and failure to identify this prior to access placement can result in devastating steal or ischemic hand symptoms. Additionally, venous mapping could conceivably encompass multiple methods when, in fact, a duplex scan should be specified. We also note that, if a unilateral study fails to reveal adequate anatomy, the ordering physician will request the study be extended to include the contralateral arm. Significantly, this occurs regularly. Therefore, we would suggest that a bilateral descriptor should also be created.

In view of these concerns, we propose different descriptors that would include an evaluation of both the arterial inflow and venous size and outflow, with provision for a bilateral examination, if clinically necessary. Our proposal remains consistent with the non-invasive vascular testing family of codes.

Accordingly, we recommend two codes, described as follows;

- Duplex scan of extremity arteries and veins for hemodialysis access placement; complete bilateral study
- Duplex scan of extremity arteries and veins for hemodialysis access placement; unilateral or limited study

Our members note that these examinations can prove extremely time consuming, as much smaller veins are being evaluated in comparison to a typical leg examination (the most common usage of 93971). It is clear that assigning the new G-code technical and professional RVUs equivalent to the limited venous duplex (93971) would seriously undervalue a study that evaluates both veins and arteries in the proposed extremity. The under

valuation would be particularly marked in connection with the technical component. A closer analogue to this service, in terms of the time required, would be 93990, though there are significant differences.

For the proposed mapping, a significant number of additional vessels would need to be interrogated, including both the deep and superficial veins, as well as all major upper arm and forearm arteries even into the palmar arch. Therefore, we suggest a RVU value of 25% more than that of the 4.27 global RVU's for 93990, for a global value of 5.34. In order to remain consistent within the noninvasive vascular family of codes, we suggest a bilateral examination be valued 50% more at 8.01 RVU's.

Finally, we also note that CMS has made several proposed amendments that require providers to meet certain minimum qualifications and training standards. As a member of the Coalition for Quality in Ultrasound, which is dedicated to extending the many Local Medical Review Policies that require vascular ultrasound services to be provide by an accredited laboratory or credentialed technologists, we strongly support CMS' belief that "minimum qualification and training requirements will assist in ensuring the quality of services provided to beneficiaries" and ensure that only reasonable and necessary services are provided. We urge CMS to make vein mapping services payable only where the accreditation or credentialing standard is met, as this is the requirement in the clear majority of Medicare carrier jurisdictions for all other vascular ultrasound services.

We greatly appreciate the opportunity to comment on the proposed rule. Please feel free to contact us should you have any questions.

Sincerely yours,

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Government Relations Chair,
Society for Vascular Ultrasound

cc: Terrence Kay, CMS
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