



October 10, 2006

Mark McClellan, M.D., Ph.D., Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

RE: CMS-1506-P: Medicare: Hospital Outpatient Prospective  
Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

On behalf of the Society for Vascular Ultrasound (“SVU”), thank you for the opportunity to comment on the proposed rule released by the Centers for Medicare and Medicaid Services (“CMS”) regarding the proposed Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (the “Proposed Rule”).<sup>1</sup> The SVU is a professional society comprised of over 4,100 registered 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 diagnostic imaging modality that uses sound waves to obtain images of the interior of the body. It 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. As a result, both primary care and specialty physicians rely on ultrasound as their chief, 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. We are pleased that Medicare will be covering ultrasound screening for AAA.

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<sup>1</sup> 71 Fed. Reg. 49,506 (Aug. 23, 2006).

We thank you in advance for consideration of our comments regarding the proposed reimbursement and the definition of "ultrasound screening for an Abdominal Aortic Aneurysm".

## **I. Appropriate Reimbursement**

We write in support of the proposed addition of ultrasound screening for Abdominal Aortic Aneurysm ("AAA"). SVU commends CMS for proposing to pay for ultrasound screening for AAAs through the use of a new HCPCS code GXXXX (Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening) on equivalent hospital resources and intensity to those contained in CPT code 76775, which is assigned to APC 0266 (Level II Diagnostic and Screening Ultrasound) for CY 2007. We agree that the hospital costs associated with the screening study are very similar to those of the limited retroperitoneal ultrasound diagnostic examination. Therefore, SVU supports the proposal to assign the screening and diagnostic studies to the same clinical APC for reasons of clinical and resource homogeneity.

## **II. Definition of "ultrasound screening for an Abdominal Aortic Aneurysm"**

Section 5112(a)(2) of the DRA defines the term "ultrasound screening for an Abdominal Aortic Aneurysm" as "(1) a procedure using sound waves (or other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and (2) includes a physician's interpretation of the results of the procedure." The statute remains silent with regard to the qualifications of individuals and facilities who perform the ultrasound screening, but in February of 2005, the United States Preventative Services Task Force ("USPSTF") recommended that screenings be performed in an accredited facility with credentialed technologists.<sup>2</sup> As a result, we strongly encourage CMS to consider including language aimed at improving the quality of ultrasound screenings provided.

We cannot overstate the importance of requiring that screenings be performed in an accredited facility with credentialed technologists. Clinical research has demonstrated that ultrasounds can be wrong as often as they are correct—upwards of a fifty percent error rate—where they are not performed with adequate quality standards in place.<sup>3</sup> Ultrasound credentialing and accreditation are well-established

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<sup>2</sup> U.S. Preventive Services Task Force. *Screening for Abdominal Aortic Aneurysm: Recommendation Statement*. AHRQ Publication No. 05-0569-A, February 2005. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/uspstf05/aaascr/aaars.htm>.

<sup>3</sup> O. William Brown et. al., *Reliability of extracranial carotid artery duplex ultrasound scanning: Value of vascular laboratory accreditation*, 39 *Journal of Vascular Surgery* 2, at 366 (2004); David G. Stanley, *The Importance of Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Certification for Non-invasive Peripheral Vascular Tests: The Tennessee Experience*, 28 *Journal of Vascular Ultrasound* 2, at 65 (2004).

standards within the Medicare program, with 37 jurisdictions requiring the credentialing of sonographers or vascular technologists.

The accuracy of noninvasive vascular diagnostic studies, like ultrasound screening, depends on the knowledge, skill and experience of the vascular technologist or sonographer, the interpreter, and the laboratory in which the service is provided. Consequently, the providers must be capable of demonstrating documented academic training and educational experience and maintain documentation for post-payment review purposes.

The addition of language regarding accreditation and/or credentialing would take an important step in protecting the health of Medicare beneficiaries, requiring that anyone performing an "ultrasound screening for an Abdominal Aortic Aneurysm" with the intention of receiving Medicare reimbursement must either be credentialed or work in an accredited laboratory. The credentialing process ensures a minimum standard of competence and experience by the individual performing the ultrasound. Accreditation of laboratories, which is an alternative to credentialing under this language, provides a means of ensuring that the ultrasound laboratory operates under appropriate standards.

Accordingly, we encourage CMS to include in the definition of "ultrasound screening for an Abdominal Aortic Aneurysm" a requirement that all studies must meet one of the two following standards: "(a) the services are performed in facilities with laboratories accredited by an appropriate national accreditation body, and/or (b) the services are performed by non-physician personnel who have demonstrated minimum entry level competency by being credentialed by an appropriate national credentialing body in vascular technology or abdominal sonography." This language would have no application to physicians who provide the technical component of an ultrasound screening for a AAA, but it would significantly improve the quality of the screening provided and ultimately the accuracy of physicians' diagnosis. On behalf of Medicare beneficiaries, we urge you to consider its inclusion.

### **III. Conclusion**

Thank you again for your consideration of our comments regarding the Proposed Rule. Again, we commend your proposal regarding reimbursement and urge you to consider language to improve the quality of ultrasound screenings provided as part of the AAA benefit. CMS and its staff continue to act in the best interests of beneficiaries and in a fashion that supports adequate and appropriate access to important health care services. Our organization and its members are very grateful for CMS' commitment to act in the best interests of beneficiaries and their access needs.

We appreciate your thorough review of our comments and hope that you will consider these in addition to those we included in our comments regarding the

Medicare Physician Fee Schedule for CY 2007. SVU would be happy to provide additional information on ultrasound screening for AAAs. We look forward to continuing to work with you to improve the health of Medicare beneficiaries.

Respectfully submitted,

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Society for Vascular Ultrasound