202

SVU

SOCIETY FOR VASCULAR ULTRASOUND

October 10, 2006

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

RE: CMS-1321-P: Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Administrator 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 Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B ("Proposed Rule").[1]

Though supportive of some aspects of the Proposed Rule, we are torn by its contents. Primarily, this is a function of our fear that the application of the outpatient prospective payment system ("OPPS") rates will have a devastating impact on beneficiary access to vascular ultrasound services. We strongly support the proposed addition of ultrasound screening for Abdominal Aortic Aneurysm ("AAA"), but we are deeply concerned that its impact on beneficiaries may be obscured by the overall impact of the proposed imaging cuts.

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,

[1] 71 Fed. Reg. 48,982 (Aug. 22, 2006).

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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. With this in mind, we offer these comments from the perspective of vascular ultrasound.

In summary, SVU presents the following comments for consideration regarding the Proposed Rule:

- **DRA Proposals: Imaging Cuts**—We write with grave concerns regarding beneficiary access to vascular ultrasound services resulting from the impact of the proposed reduction in technical component ("TC") for imaging services under the physician fee schedule ("PFS"). We urge CMS to alleviate the disproportionate impact of these cuts on vascular ultrasound services by excluding from implementation those services that fall outside of the definition of "imaging".

- **DRA Proposals: Ultrasound Screening Benefit for AAA**—We applaud CMS for its proposals regarding the addition of ultrasound screening for AAA and urge the Agency to consider our suggestion to improve the quality of ultrasounds provided through this new benefit.

- **IDTF Issues**—In lieu of the proposed IDTF performance standards, we encourage CMS to consider requiring that all services are performed in facilities with laboratories accredited by an appropriate national accreditation body.

- **Reassignment and Physician Self-Referral**—We fear the proposal to amend the regulations to clarify reassignment pursuant to the contractual arrangement exception may be unnecessarily broad and should exclude vascular ultrasound. Also, in proposing a square footage requirement, we fear that CMS may have overlooked the size of the typical vascular ultrasound lab, and we respectfully request that CMS consider exempting all vascular ultrasound labs from the square footage requirement.

- **Provisions**—SVU notes that CMS is not proposing to update the contents and prices for vascular ultrasound "rooms". We are generally pleased with the calculation for vascular ultrasound "rooms" and do not see the need to reevaluate their contents and pricing at this time.

We thank you in advance for consideration of our comments on the Proposed Rule, which are discussed at greater length below.

I. DRA Proposals

The SVU offers the following comments related to provision of the Deficit Reduction Act of 2005 ("DRA").[2] We write with tremendous concern about the proposed reduction in the TC for imaging services under the physician fee schedule and the devastating impact on beneficiary access to vascular ultrasound services we fear will result. But, we applaud CMS for its proposals regarding the addition of ultrasound screening for AAA.

A. Section 5102—Proposed Adjustments for Payments to Imaging Services

SVU is deeply concerned by the potential impact on beneficiary access to vascular ultrasound services that may result from the impact of the proposed reduction in TC for imaging services under the PFS. As required by section 5102(b)(1) of the DRA, CMS will cap the PFS payment amount for imaging services furnished on or after January 1, 2007, prior to geographic adjustment, by the CY 2007 OPPS payment amount, prior to geographic adjustment. However, CMS should not and, indeed, cannot include some vascular technology services in its implementation of the DRA, because those services are not "imaging" services within the meaning of the DRA.

The DRA is specifically limited to "imaging services" performed using various modalities, including "ultrasound". The use of "ultrasound", however, is not enough to make the DRA applicable. The service must be an "imaging service".[3] Accordingly, the accurate identification of non-invasive vascular studies as either "imaging" or "non-imaging" procedures is critical to the appropriate implementation of the DRA in compliance with the plain language of the statute and the intent of Congress.

The courts have been clear in a series of cases that the plain language of a statute must be honored by a regulatory agency.[4] Regulatory agencies do not have the discretion to deviate from the plain language of a statute. We urge CMS to act within the confines of the statute to minimize the disproportionate impact on vascular ultrasound services.

In determining the Current Procedural Terminology ("CPT") and alpha-numeric Healthcare Common Procedure Coding System ("HCPCS") codes that fall within the scope of "imaging services" defined by the DRA provision, we understand that CMS considered the CPT 7XXXX series codes for radiology services and then added in

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[2] Pub. L. No. 109-181 (2006).

[3] *See id.* at §5102.

[4] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted).

other CPT codes and alpha-numeric HCPCS codes that describe imaging services, excluding a number of services.

Along with the Society for Vascular Surgery ("SVS") and the Society of Diagnostic Medical Sonography ("SDMS"), we commissioned a report by the Lewin Group regarding the impact of the DRA on vascular ultrasound services. Lewin calculated the potential reimbursement loss as a result of the DRA to the 252 imaging HCPCS codes spanning 19 APCs based on the DRA mandate and the frequency of these HCPCS codes performed in a PFS environment. According to Lewin, 25 vascular codes in three APCs account for almost 24 percent ($182 million) of the Lewin estimated over $770 million reduction in reimbursement for imaging services in a PFS environment.

This finding reveals that 24 percent of the effect of DRA is attributed to just 25 of 252 codes or less than 10 percent of the affected codes. Significantly, the $770 million impact that Lewin identified for the DRA is approximately $220 million more than the Congressional Budget Office ("CBO") estimates of the DRA impact, even though the CBO estimate considered the various imaging components of the DRA, and not just the hospital outpatient department ceiling component of the DRA. A complete copy of the Lewin report, "Impact of the DRA on Vascular Ultrasound Services", is attached for your review. (See Addendum A)

Below, we discuss three sets of procedures—physiologic, Transcranial Doppler ("TCD"), and duplex—that we believe should be excluded from the reduction in TC for imaging services under the PFS because they fall outside of the definition of "imaging" in whole or in part. SVU believes that the Lewin finding suggests that significant relief can be given to rescue these procedures without preventing the level of savings that Congress intended. We encourage you to consider these proposals carefully.

1. Physiologic procedures

We believe that CMS should not include some vascular technology services in its implementation of the DRA because those services are not "imaging" services within the meaning of the DRA. We ask that you include this important point in the PFS final rule. The DRA is specifically limited to "imaging services" performed using various modalities, including "ultrasound". The use of "ultrasound", however, is not enough to make the DRA applicable. The service must involve "imaging".[5]

The accurate identification of non-invasive vascular studies as either "imaging' or "non-imaging" procedures is critical to the accurate implementation of the DRA in compliance with the plain language of the DRA and the intent of Congress. It is clear that both "imaging" and "non-imaging" procedures are included in the Non-Invasive Vascular Diagnostic Studies section of the AMA CPT codebook (98375 through 93990 inclusive). The introduction to the non-invasive vascular diagnostic studies

[5] *See* Pub. L. No. 109-181 at §5102.

section of the CPT codebook reflect the difference between "imaging" and "non-imaging" services in its descriptions of both "duplex scan" and "noninvasive physiologic studies":

> "Duplex scan (e.g., 93880, 93882) describes an ultrasonic scanning procedure for characterizing the pattern and direction of blood flow in arteries or veins with the production of real time images integrating B-mode two-dimensional vascular structure with spectral and/or color flow Doppler mapping or imaging.
>
> Non-invasive physiologic studies are performed using equipment separate and distinct from the duplex scanner. Codes 93875, 93965, 93922, 93923, and 93924 describe the evaluation of non-imaging physiologic recordings of pressures, Doppler analysis of bi-directional blood flow, plethysmography, and/or oxygen tension measurements appropriate for the anatomic area studied."[6]

The following CPT codes correspond to "non-invasive physiologic studies". Each begins with the terminology "non-invasive physiologic studies" and is not an imaging procedure:

- 93875 Non-invasive physiologic studies of extracranial arteries, complete bilateral study (eg, periorbital flow direction with arterial compression, ocular pneumoplethysmography, Doppler ultrasound spectral analysis)
- 93922 Non-invasive physiologic studies of upper or lower extremity arteries, single level, bilateral (eg, ankle/brachial indices, Doppler waveform analysis, volume plethysmography, transcutaneous oxygen tension measurement)
- 93923 Non-invasive physiologic studies of upper or lower extremity arteries, multiple levels or with provocative functional maneuvers, complete bilateral study (eg, segmental blood pressure measurements, segmental Doppler waveform analysis, segmental volume plethysmography, segmental transcutaneous oxygen tension measurements, measurements with postural provocative tests, measurements with reactive hyperemia)
- 93924 Non-invasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, complete bilateral study

[6] Current Procedural Terminology Professional Edition 2006, AMA at 388.

- 93965 Non-invasive physiologic studies of extremity veins, complete bilateral study (eg, Doppler waveform analysis with responses to compression and other maneuvers, phleborheography, impedance plethysmography)

These studies simply do not produce an "image". For this reason, we do not believe that there is any basis to include the physiologic codes in the DRA implementation. Consistent with the constraints imposed on the Agency by the plain language of the DRA, we urge you to exclude them from the application of this provision consistent with the plain language of the statute.

2. TCD procedures

Similarly, the TCD codes should be excluded from the DRA implementation because an "image" is not inherently a part of those services. A description of TCD is provided in the introduction to the cerebrovascular arterial studies section of the CPT codebook:

> "A complete transcranial Doppler (TCD) study (93886) includes ultrasound evaluation of the right and left anterior circulation territories and the posterior circulation territory (to include vertebral arteries and basilar artery). In a limited TCD study (93888) there is ultrasound evaluation of two or fewer of these territories. For TCD, ultrasound evaluation is a reasonable and concerted attempt to identify arterial signals through an acoustic window."[7]

It is critical to note that there is no reference to "real time images" or "imaging" in this language. The term "duplex scan" specifically includes both of these references. TCD is not inherently or necessarily or traditionally an imaging service.

Since the introduction of TCD in 1982, numerous applications have been identified for conventional (non-imaging) TCD with relatively little application for the more recent development of TCD imaging. In 1990-1991, when SVU was working with Barton C. McCann, MD, then a Medical Director of CMS (then the Health Care Financing Administration) and member of the AMA CPT Editorial Panel, on revision of the CPT codes for non-invasive vascular studies, the decision was deliberately made not to use the term "duplex scan", with its imaging references. As such, the following two CPT code descriptors were published in 1992:

- 93886 Transcranial Doppler study of the intracranial arteries; complete study

[7] *Id.*

- 93888 Transcranial Doppler study of the intracranial arteries; limited study

The term "study" was intentionally chosen to distinguish these codes from the inherently "imaging" focused nature of all "duplex scans." More recently, in 2005, the following TCD CPT codes were added, again reflecting a deliberate decision not to use the term "duplex scan" in connection with a TCD service:

- 93890 Transcranial Doppler study of the intracranial arteries; vasoreactivity study
- 93892 Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection
- 93893 Transcranial Doppler study of the intracranial arteries; emboli detection with intravenous microbubble injection

The available evidence underscores the fact that imaging is not inherent to or normally and typically associated with a TCD service. A number of reasons can be cited to support our conclusion that TCD procedures are traditionally and typically performed with conventional static pulsed wave Doppler transducers, as opposed to any "duplex" or "imaging" systems. For example, the success rate in obtaining data from specific intracranial arteries, most notably via the transtemporal approach, which is the approach used for evaluation of the anterior, middle and posterior cerebral arteries, has long been known to be higher using a non-imaging approach, than using an imaging one. Given this well-known clinical reality, there is absolutely no reason, we believe, to conclude that imaging plays any significant role in TCD services. In 1994, Fujioka, et al. published a comparison of traditional non-imaging TCD with the imaging approach assessing intracranial hemodynamics in a patient population with a mean age of 65 years.[8] They found transtemporal success rates 76 percent for traditional non-imaging TCD, versus 52 percent when an imaging approach is undertaken.

Monitoring procedures, whether intraoperative, for assessment of cerebrovascular reactivity, or emboli detection, require prolonged acquisition of Doppler ultrasound signals, which is technically challenging. Consequently, head-gear that allows for fixed placement of a TCD transducer is often used. We are unaware of any head-gear that is designed for use with an imaging approach. Even when head-gear is unavailable, conventional TCD transducers are typically used given they are relatively easier to control and hold in position, causing less operator stress. We are not aware that any manufacturer of duplex scan equipment has developed an imaging transducer for TCD.

[8] Fujioka K, Gates D, Spencer M: *A comparison of Transcranial Color Doppler Imaging and Standard Static Pulsed Wave Doppler in the Assessment of Intracranial Hemodynamics.* JVT 18(1)29-35, 1994.

We were pleased to see that the Proposed Rule contemplated a circumstance similar to that presented by TCD. In fact, CMS has already excluded any services where the CPT code describes a procedure for which ultrasound is employed peripherally in the performance of the main procedure.[9] CMS cites two examples: 31622 for bronchoscopy with or without fluoroscopic guidance; and 43242 for upper gastrointestinal endoscopy with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s).[10] The Proposed Rule goes on to explain the rationale for excluding these procedures by stating: "In these cases, we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality . . .".[11] Based on the evidence presented above, it is clear to us that CMS should exclude the TCD codes under the same reasoning. In our view, CMS cannot exclude 31622 and 43242 and include the TCD services in any rational or consistent manner.

For these reasons, CMS should recognize the TCD codes as non-imaging codes. We very much hope that in its final rule CMS will exclude 93886, 93888, 93890, 93892, and 93893 from the reduction in TC for imaging services, given the DRA's explicitly limited, "imaging" focus.

3. Duplex procedures

Duplex codes describe combination services that are both "non-imaging" and "imaging" components. In addition to the physiologic and TCD codes discussed above, we have concluded that the DRA is inapplicable to at least a portion of the duplex codes as well. A portion of the duplex code services are clearly physiologic services and not any more an "imaging" service than the physiologic codes themselves.

Similar to the our reasoning noted above regarding TCD, we urge CMS to exclude these services because the CPT code describes a procedure for which ultrasound is employed peripherally in the performance of the main procedure. We believe that "the use of an imaging technology cannot be segregated from the performance of the main procedure."[12] As a result, we urge you to exclude these duplex procedures entirely or, alternatively, isolate the portion of PFS duplex reimbursements that relate to physiologic services and ensure that that portion of the reimbursement is not reduced by the DRA.

The introduction to the non-invasive vascular diagnostic studies section of the CPT codebook reflects the difference between "imaging" and "non-imaging" services in its descriptions of "duplex scan" services. The AMA CPT manual states the following:

[9] 71 Fed. Reg. at 48,997.
[10] *Id.*
[11] *Id.*
[12] *Id.*

> "Vascular studies include patient care required to perform the studies, supervision of the studies and interpretation of study results with copies for patient records of hard copy output with analysis of all data, including bidirectional vascular flow or imaging when provided."[13]

Significantly, this language specifically draws a distinction between "bidirectional vascular flow" data and "imaging" data. The "or" in the sentence clearly emphasizes that both "non-imaging" and "imaging" services are described by the code.

A "duplex scan" includes both the collection of physiologic data in the form of Doppler analysis of bi-directional blood flow, the spectrum analysis, as well as real-time B-mode imaging. Spectrum analysis typically includes Fast Fourier Transform analysis of the Doppler shifted frequencies from moving blood cells with a time varying (on the x-axis) frequency/velocity (on the y-axis) and amplitude being displayed in shades of gray, this being solely physiologic in nature.

As such, duplex scanning includes both components of physiologic procedures as well as imaging studies. The majority of diagnostic information for duplex scans is based on physiologic data in the form of findings from Doppler spectrum analysis. This includes Doppler shifted frequencies, blood flow velocities, ratios of blood flow velocities and Doppler waveform characteristics that are all solely physiologic in nature. In practice, the imaging component is used largely to guide the acquisition of the physiologic Doppler data. Additionally, the interpretation of a duplex scan is performed nearly exclusively by analysis of the spectral waveform. In fact, all published diagnostic criteria are based on the physiologic data, and we are unaware of any published study that uses the "imaging" part of the duplex scan in lieu of the physiologic data for the diagnosis of vascular disease, which raises the question as to whether the duplex scan should be subject to the DRA imaging provision at all.

Significantly, the division in the vascular ultrasound services between the imaging and non-imaging components of the services is recognized in the echocardiography services, further supporting that the distinction that we cite is well-established in the CPT system. Where the vascular ultrasound codes combine three service elements into a single CPT code—B mode (an imaging service), spectral Doppler (an non-imaging service), and color flow mapping (a non-imaging service that creates a visual display of the physiologic Doppler information)—those three elements are placed into three separate codes in echocardiography. A typical echocardiography service thus includes 93307 transthoracic echo (an imaging service), 93320 Doppler echo pulsed wave, continuous wave (a non-imaging service), and 93325 color Doppler flow. Accordingly, we ask you to recognize well-established distinctions between the imaging and non-imaging components of ultrasound services.

[13] CPT Professional Edition at 388.

If CMS decides not to exclude vascular ultrasound in its entirety from the effects of the DRA, we believe that CMS must, at a minimum, isolate the non-imaging components of the duplex scan codes, and we have a basis to determine how to apportion the imaging and non-imaging portions of the services appropriately. CMS can appropriately apportion the imaging and non-imaging components of the vascular duplex codes by examining data that the SVS collected for the Practice Expense Advisory Committee ("PEAC") and used in its review of the codes. The data relates to a survey that was conducted as part of the PEAC process in late 2001 and early 2002, and SVS presented it to the PEAC in February of 2002. Significantly, the data establishes that for the leading vascular ultrasound service at least 53 percent of the service is non-imaging in nature.

In the survey of the amount of time devoted to a carotid study, CPT 93880, 45 physicians were asked for the intra-service minutes spent on saggital B-mode (an imaging service), transverse B-mode (an imaging service), color flow (a non-imaging service) and Doppler spectral data acquisition (a non-imaging service). Significantly, the survey was developed long before the DRA was passed and so there was no reason for the respondents to value one component of the service more heavily than another. Indeed, because the survey involved two questions for each site about B-mode imaging collection (saggital and transverse for each site), but only one question per site about Doppler (the non-imaging component), the survey was arguably biased in a fashion that might lead to over-reporting of imaging components of the service, as compared to non-imaging components. The 45 physician data medians for "perform exam" were: (1) saggital plus transverse B-modes 16.50 minutes (39 percent of total "perform exam" time); (2) color flow 10.25 minutes (24 percent of total "perform exam" time); and (3) Doppler spectral data 12.00 minutes (29 percent of total "perform exam" time). Thus, the non-imaging components account for, under this analysis, a majority of the service (53 percent).[14]

More recent data, which SVS has made available to you, establishes, that, on average an even higher percentage of vascular services reflect non-imaging services. Part of SVS's data, for instance, indicates that total technologist time for 93880 is 82 minutes and that only 26.75 of those minutes are imaging. If CMS subtracts the 26.75 minutes for the B-mode imaging service from the 82 total minutes, the resulting number could be used to proportion the RVUs between the imaging and non-imaging components of the service. Based on this data, 67 percent of 93880 is physiologic and should be recognized as non-imaging. SVS's data, for some services, shows the non-imaging components to exceed 67 percent.

Because the majority of vascular ultrasound services are not imaging in nature and because of the disproportionate effect that the DRA would otherwise have on

[14] We have included two excel spreadsheets for your review. One includes the raw data from the 93880 survey respondents. (See Addendum B) The other is the Cumulative Time spreadsheet submitted to the PEAC in 2002. (See Addendum C)

these services, we believe that CMS should eliminate them from the DRA. We believe that such treatment would be consistent with the Proposed Rule where it states that services are not properly subject to the DRA and should be excluded where "the use of an imaging technology cannot be segregated from the performance of the main procedure."[15] CMS should apply this approach consistently in its final rule.

In the alternative, to the extent that the non-imaging components of ultrasound services can, in CMS' view, be segregated from the imaging components, based on the data SVS has presented, we urge CMS to carve out only the minutes, and relative value units ("RVUs"), directly attributable to the imaging components of these services.

To calculate the reduction in the TC RVUs, CMS would follow the steps below:

Step 1: Total technologist minutes now in CMS database for 93880 = 82 min

Step 2: Total minutes according to the data we collected that are assigned to imaging under "perform exam" = 26.75 min

Step 3: Total minutes for 93880 study after carving out imaging minutes = 82.00 - 26.75 = 55.25

Step 4: Percentage of time for complete study after imaging minutes have been carved out = 55.25 / 82.00 = 67.4%

Step 5: Percentage of time susceptible to imaging cuts = 100% - 67.4% = 32.6%

Step 6: Reduction in technical payment due to DRA if entire study were imaging = MFS - APC = $217 - $152 = $65

Step 7: Reduction in technical payment due to DRA since only 32.6% of study is imaging = $65 x 0.326 = $21

Step 8: Reduction in technical payment adjusted for imaging portion = $217 - $21 = $196

[15] 71 Fed. Reg. at 48,997.

Step 9: Reduction in technical RVUs would be
$21/$37.90 = 0.55 RVUs

Step 10: Current TC RVU for 93880 = 5.72

Step 11: Adjusted TC RVU after imaging time carve-out = 5.72 - 0.55 = 5.17

Although we believe that ultrasound services should be eliminated from the DRA entirely, we believe, at the very least, that any segregable component of these services must be protected from any reduction in payment, consistent with CMS' own Proposed Rule.

Based on this analysis, the following duplex scan procedures must be excluded, either in whole or in part, from any DRA reductions:

- 93880 Duplex scan of extracranial arteries; complete bilateral study
- 93882 Duplex scan of extracranial arteries; unilateral or limited study
- 93925 Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study
- 93926 Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study
- 93930 Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study
- 93931 Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study
- 93970 Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
- 93971 Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study
- 93975 Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study

- 93976 Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study
- 93978 Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study
- 93979 Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study
- 93980 Duplex scan of arterial inflow and venous outflow of penile vessels; complete study
- 93981 Duplex scan of arterial inflow and venous outflow of penile vessels; follow-up or limited study
- 93990 Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)

We very much hope that you will exclude the portion of the reimbursements for the duplex codes that are not "imaging" in nature.

4. Conclusion

Given the disproportionate impact of these cuts on vascular ultrasound, we hope that you will consider this proposal to exclude the physiologic, TCD, and duplex codes in whole, or in part, from the reduction in TC for imaging services under the PFS because they fall outside of the definition of "imaging". We believe that the Lewin finding suggests that significant relief can be given to exclude these procedures without preventing the level of savings that Congress intended, and we thank you in advance for your review of this proposal.

B. Section 5112—Proposed Addition of Ultrasound Screening for Abdominal Aortic Aneurysm ("AAA")

We applaud CMS for its proposals regarding the addition of ultrasound screening for AAA. SVU believes that the thoughtful consideration given to its implementation, particularly the addition of language to the regulations that would allow for CMS to make determinations through the national coverage determination ("NCD") process, will go a long way to detect and treat AAAs. We offer the following comments regarding the proposed scope and reimbursement of this benefit.

1. Scope of the AAA Screening Benefit

SVU was pleased that Section 5112 of the Deficit Reduction Act ("DRA") of 2005 amended section 1861 of the Social Security Act to provide for coverage under

Medicare Part B of ultrasound screening for AAAs. Our members look forward to providing ultrasound screenings to Medicare beneficiaries as part of this new benefit. We thank CMS for its well-reasoned implementation of this benefit and offer the following comments regarding the definition of "ultrasound screening for an Abdominal Aortic Aneurysm" and "eligible beneficiary".

a. 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.[16] 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.[17] Ultrasound credentialing and accreditation are well-established 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 technologist or sonographer, the interpreter, and the laboratory in which the service is provided. Consequently, the providers must be capable of demonstrating documented training and experience and maintain documentation for post-payment review purposes.

The addition of language regarding accreditation and/or credentialing would be an important step in protecting the health of Medicare beneficiaries, requiring

[16] 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.

[17] 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).

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." 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.

b. Definition of "eligible beneficiary"

We find the proposed definition of "eligible beneficiary" to be consistent with Congressional intent. SVU is particularly pleased that CMS has also opened the door to expanded coverage with this proposal by adding individuals who manifest "other risk factors that are described in a benefit category recommended by the USPSTF regarding an AAA that has been determined by the Secretary through the NCD process" to the definition of "eligible beneficiary". We agree that this will facilitate possible expansions of coverage in the future. In the event that CMS considers alternative screening technologies to ultrasound screening for AAAs of commensurate accuracy and cost, we look forward to working in concert with the Agency to ensure that potential changes remain in the best interests of Medicare beneficiaries.

2. Appropriate Reimbursement

Beginning January 1, 2007, CMS is 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). We are pleased that CMS is proposing that payment for this service be made at the same level as CPT code 76775 (Ultrasound, retroperitoneal (eg, renal, aorta, nodes), B-scan and/or real time with image documentation; limited). CPT code 76775 is used to bill for the service when it is provided as a diagnostic test, and we agree the service associated with the proposed HCPCS code reflects equivalent resources and work intensity to those contained in CPT code 76775.

3. Conclusion

In summary, SVU commends CMS for its proposals regarding the addition of ultrasound screening for AAA. We strongly encourage CMS to consider including language in the definition of "ultrasound screening for an Abdominal Aortic Aneurysm" aimed at improving the quality of ultrasound screenings provided. In addition, we applaud the latitude provided in the proposed definition of "eligible beneficiary". SVU agrees with the payment of new HCPCS code GXXXX at the same level as CPT code 76775 and believes that appropriate reimbursement takes a positive step toward ensuring beneficiary access to this potentially life-saving screening.

II. IDTF Issues

Quality of care is perhaps the SVU's highest priority. Our discussion above in the context of the AAA screening benefit outlines the importance of requiring that screenings be performed in an accredited facility with credentialed technologists. We take this opportunity to reiterate that clinical research has demonstrated that ultrasounds can be wrong as often as they are correct when they are not performed with adequate quality standards in place. The accuracy of noninvasive vascular diagnostic studies, like ultrasound screening, depends, in large part, on the laboratory in which the service is provided.[18] We strongly believe that all providers, including IDTFs, must be capable of demonstrating documented training and experience and maintain documentation for post-payment review purposes.

We encourage CMS to closely monitor the quality of care provided to Medicare beneficiaries. SVU takes seriously any improper billing of the Medicare program by a provider, including an IDTF. We believe that CMS is well-intentioned in proposing that each IDTF be required to be in compliance with the proposed fourteen supplier standards in order to obtain or retain enrollment in the Medicare program. We agree that some benchmarks are necessary to ensure that minimum quality standards are met to protect beneficiaries as well as the Medicare Trust Fund and that the proposed standards are merely good business practices.

While we appreciate that a primary business phone number and address speak to prudent business practices in some respects, we are not persuaded that proposed standards will help to ensure that suppliers are providing quality care to Medicare beneficiaries. These proposed standards speak to the legitimacy of the businesses but generally fail to address the quality of care actually provided. In fact, it may be a misnomer to refer to these proposals as "performance standards" of any kind.

We believe that proposed supplier standard number 12 is the only one that speaks directly to the issue of quality of care, stating: "Have technical staff on duty with the appropriate credentials to perform tests. The IDTF would be required to produce the

[18] *See* Brown and Stanley, *supra.*

applicable Federal or State licenses and/or certifications of the individuals performing these services".[19] While this standard takes a step in the right direction, and although we strongly support the standard, SVU believes these proposed "performance" standards fall short of ensuring the appropriate quality of care, largely because the IDTF regulation already requires that IDTFs employ state-licensed technologists or, in the absence of state licensure, credentialed personnel.

In lieu of the proposed performance standards, we encourage CMS to consider requiring that all IDTFs be accredited by an appropriate national accreditation body. Accreditation of laboratories provides a means of ensuring that the ultrasound laboratory operates under appropriate standards. It focuses on the quality of services provided and not simply the business practices of the facility. If an IDTF fails to obtain accreditation at the time of enrollment or at the time of re-enrollment, then its enrollment application would be denied. Similarly, if at any time an enrolled IDTF loses its accreditation, its billing privileges would be revoked.

The Intersocietal Commission for the Accreditation of Vascular Laboratories ("ICAVL") is an example of one of the accrediting bodies that CMS could rely upon to ensure that minimum quality standards are met to protect beneficiaries as well as the Medicare Trust Fund. ICAVL's mission is to promote high quality noninvasive vascular diagnostic testing in the delivery of health care by providing a peer review process of laboratory accreditation. Their expertise in this area and the rigor involved in the accreditation process is evidenced by their accreditation standards. We are attaching for your review a copy of the ICAVL organization standards. (See Addendum D) All laboratories must meet these standards and may apply in any combination of the other areas, as suited to the services offered by each laboratory.

SVU hopes that you will seriously consider accreditation as an alternative to the proposed performance standards. Our proposal is crafted with CMS' limited resources in mind. When there are already bodies set up to ensure the quality of IDTFs for Medicare enrollment purposes, it would seem duplicative for CMS to undertake the assessment of these issues. By adopting an accreditation standard, CMS can secure appropriate standards and have the accreditation bodies bear the cost of enforcing those standards. This model has clearly worked well in the hospital context, and it should be used here. Significantly, all of the meaningful proposed supplier standards would be enforced by an accreditation body, such as a physical inspection to ensure a bona fide address. We respectfully request that you comprehensively review this proposal.

III. Reassignment and Physician Self-Referral

The proposed changes to reassignment and physician self-referral rules relating to diagnostic tests present two concerns for SVU. First, while we appreciate the proposal to amend 42 C.F.R. § 424.80 to clarify reassignment pursuant to the contractual

[19] 71 Fed. Reg. at 49,602.

arrangement exception, we believe that the proposal should address the specific issues of "pod" clinical laboratories that we understand gave rise to the proposal. Second, we write with concern regarding the proposed change to the definition of "centralized building" at 42 C.F.R. §411.351, which we believe will have unintended consequences for vascular ultrasound laboratories.

A. Program Integrity Safeguards Relating to the Right to Payment for Diagnostic Tests

As we understand it, CMS' proposals to amend 42 C.F.R. § 424.80 to clarify reassignment pursuant to the contractual arrangement exception involve three primary elements. In this section, we summarize and then comment on these reassignment proposals.

First, CMS would amend § 424.80 to provide that if the TC of a diagnostic test is billed by a physician or medical group under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts: (1) the physician or other supplier's net charge to the billing physician or medical group; (2) the billing physician's or medical group's actual charge; and, (3) the fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

Second, CMS proposes to require that, in order to bill for the TC, the billing entity would be required to perform the interpretation.

Third, CMS is considering, but not proposing, certain conditions regarding when a physician or medical group can bill for a reassigned PC for a diagnostic test. In addition to the first two existing Claims Processing Manual requirements that must be satisfied in order to submit a claim for a purchased diagnostic test interpretation, CMS is now considering an amendment to the third condition such that that the physician or medical group billing for the interpretation must have performed the TC.

Given that, as we understand it, CMS' proposal seems to focus on issues that relate to clinical laboratory "pod labs", we believe that these changes should be limited to those labs. To the extent that CMS decides to apply these possible requirements more broadly, we believe that they should not, in any event, apply to ultrasound services. Finally, to the extent that CMS does potentially apply these requirements to ultrasound services, CMS should make clear that they do not apply where a physician or supplier uses leased subcomponents to itself provide a TC service. In such a case, even though subcomponents of the service may be provided using leased elements, the physician who ultimately delivers that service is the provider of the service and may bill for it without a reassignment.

B. Definition of "Centralized Building"

We also write with concern regarding the proposed change to the definition of "centralized building" at 42 C.F.R. §411.351. As we understand it, this proposal related to "pods" would place certain restrictions on what types of space ownership or leasing arrangements will qualify for purposes of the physician self-referral in-office ancillary services exception and physician services exception. In particular, we find problematic the proposal to modify the definition of "centralized building" to include a minimum square footage requirement of 350 square feet.

In proposing a square footage requirement, we fear that CMS may have overlooked inadvertently the size of the typical vascular ultrasound lab, which average between 230 and 300 square feet in size. We appreciate that this proposal is aimed at preventing abusive arrangements, while not disqualifying legitimate, stand-alone physician offices, like vascular labs, that are unusually small. First, we respectfully request that CMS consider exempting all vascular ultrasound labs from the square footage requirement. In lieu of a complete exemption, second, we strongly suggest that CMS create a vascular ultrasound lab exception with a 200 square foot requirement. Third, if CMS is not inclined to create a vascular lab exception, we urge the Agency to consider lowering the requirement for all labs to 200 square feet. In the absence of an exception or reduction of square footage, we fear that vascular ultrasound labs will be unfairly penalized for the smaller nature of their labs. We thank you for carefully considering the application of the proposal to vascular ultrasound. As written, we believe this proposal will have unintended consequences, and we hope that you will consider a refinement.

IV. Provisions

As part of the discussion of resource-based practice expense ("PE") RVU proposals for CY 2007, CMS discusses the definition of "imaging rooms" along with the treatment of other imaging issues. In addition to accepting the American College of Radiology ("ACR") pricing information for certain imaging equipment previously presented in the CY 2006 PFS proposed regulation, we appreciate that CMS is proposing to update five imaging "rooms"—including basic radiology, radiographic fluoroscopy, mammography, computed tomography ("CT") , and magnetic resonance imaging ("MRI") rooms. We note that CMS is <u>not</u> proposing to update the contents and prices for vascular ultrasound "rooms". The SVU is generally pleased with the calculation for vascular ultrasound "rooms" and does not see the need to reevaluate their contents and pricing at this time. We look forward to an opportunity to comment on the valuation of vascular ultrasound "rooms" should the need to update the contents and prices arise in the future.

V. Conclusion

Thank you again for your consideration of our comments regarding the DRA proposals, reassignment and physician self-referral, and IDTF issues in the Proposed Rule. We hope that CMS will consider alleviating the disproportionate impact of proposed reduction in TC for imaging services on vascular ultrasound services by excluding from implementation those codes that fall outside of the definition of "imaging". SVU respectfully requests that CMS consider exempting all vascular ultrasound labs from the proposal to clarify the terms of reassignment pursuant to the contractual arrangement exception and the square footage requirement as part of the proposed change to the definition of "centralized building". We encourage CMS to consider requiring that all services are performed in IDTFs with laboratories be accredited by an appropriate national accreditation body.

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

Respectfully submitted,

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ADDENDUM A

The LEWIN GROUP

Impact of the DRA on Vascular Ultrasound Services

Prepared for:

Society of Diagnostic Medical Sonography

Society of Vascular Ultrasound

Society for Vascular Surgery

Report Findings

July 31, 2006

Addendum A

Impact of the DRA on Vascular Ultrasound Services

Prepared for:

Society of Diagnostic Medical Sonography
Society of Vascular Ultrasound
Society for Vascular Surgery

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REPORT FINDINGS

July 31, 2006

I. BACKGROUND AND OVERVIEW

The Deficit Reduction Act of 2005 (DRA) mandates that Medicare reimbursement for imaging services performed in a physician fee schedule (PFS) environment should be based on the lesser of two payment systems, the Medicare Hospital Outpatient Perspective Payment System (HOPPS or OPPS) or the Medicare PFS, effective January 1, 2007. Our analyses reveal that the DRA reduces payment for vascular ultrasound procedures disproportionately more than other imaging procedures.[1] Explanation lies within methodology differences between the OPPS and PFS payment calculations.

The Medicare OPPS calculates payments based on groups of Health Care Financing Administration (HCFA)[2] Common Procedure Coding System (HCPCS) codes called Ambulatory Payment Classifications (APCs). According to CMS, "Services [HCPCS codes] in each APC are similar clinically and in terms of the resources they require."[3] Each HCPCS code is assigned to one APC. The HCPCS codes within an APC receive a single payment based on a calculation of the median cost of the HCPCS codes within the APC. The median costs are determined based on a hierarchy of revenue codes, or revenue centers, which provide charges for departmental cost-to-charge ratios (RCCs) as reported on the Medicare cost report as applied to "natural" single and "pseudo" single claims.[4]

The "resources" each HCPCS code requires in the OPPS rely on estimates of HCPCS costs which are based on HCPCS charges "stepped-down" to a HCPCS cost by the RCC. The level of accuracy of OPPS resource measurement is, therefore, determined by the accuracy of the RCC calculation.

The Medicare PFS provides reimbursement through a procedural relative weight assignment based on resource utilization. These weights are called relative value units (RBRVUs or RVUs). The RVUs undergo regular evaluation ensuring that each component within the RVU (physician work, practice expense, and malpractice expense) receives the appropriate weight resulting in a suitable payment for each HCPCS code.

The level of reimbursement variation between the OPPS and PFS environment differs greatly across HCPCS codes. For example, procedure 93970, Extremity Study, has a current allowance of $207.27 per procedure in a PFS environment. In a hospital outpatient setting, the same procedure is paid at the APC 0267 rate of $152.01 per procedure. The result is a $55.26 reimbursement difference per procedure with the higher payment based on the RVU of the procedure itself rather than a departmental RCC.

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[1] We understand that there is a significant legal issue posed abut whether all or all portions of vascular ultrasound procedures are imaging services within the meaning of the DRA. For purposes of this Report, we will consider the potential impact of all vascular ultrasound procedures under the DRA.

[2] Now the Centers for Medicare and Medicaid Services (CMS)

[3] CMS. Hospital Outpatient Perspective Payment System Overview. http://www.cms.hhs.gov/HospitalOutpatientPPS/ As viewed on May 1, 2006.

[4] Federal Register. 42 CFR Parts 419 and 485 Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Final Rule. Vol. 70, No 217, page 68519.

A counter example includes HCPCS code 93312, Echo Transesophageal, which receives an allowance of $154.99 under the PFS while in an outpatient setting the same procedure is paid at the APC 0270 rate of $397.90 per procedure. This results in a $242.91 payment difference per procedure.

Under DRA, performing HCPC 939701 in a PFS environment will result in reimbursement at the APC rate, $152.01, not the PFS rate of $207.27. Although reimbursement reduction is the expected result in light of the goals of the DRA, highly disproportionate payment impact among remaining imaging specialties was, as far as we can determine, unintended. Significantly, vascular ultrasound procedures produce disproportionate losses to providers in the PFS environment compared to the PFS losses across other imaging specialties.

Vascular ultrasound HCPCS codes are assigned to one of three APCs, including 0096-Non-Invasive Vascular Studies, 0266-Level II Diagnostic Ultrasound, and 0267-Level III Diagnostic Ultrasound, as shown in ***Appendix A***. The purpose of this report is to detail the reimbursement reduction to vascular imaging and present potential alternatives to the current APC assignments and payment methodology. Applicable imaging HCPCS mapped to their assigned APCs is shown in ***Appendix B***.

Our examination of the vascular ultrasound codes resulted in several findings:

1. The DRA disproportionately reduces reimbursement to vascular procedures in a PFS setting compared to other imaging codes.[5]

2. The difference between reimbursement in an OPPS setting and a PFS setting is larger for vascular services than other imaging codes. In addition, vascular ultrasound codes are consistently reimbursed at a higher rate in a PFS environment than in the OPPS environment.

3. A comparison of RVUs in vascular ultrasound codes compared to remaining imaging codes shows that median APC HCPCS costs are lower for vascular ultrasound APC HCPCS codes than other imaging APC HCPCS codes of similar RVU weight.

Based on the above findings, we explore four possible approaches designed to minimize the disproportionate reduction of reimbursement that would otherwise result from the DRA.

1. Create a new APC comprised of high frequency vascular procedure codes;

2. Re-assign vascular ultrasound procedure codes to a different APC with a higher and more appropriate APC median cost; and

[5] We have based our analysis on current PFS reimbursement levels for the vascular services. On June 29, 2006, CMS proposed a rule that would prospectively change PFS vascular service reimbursement. Although an analysis of this proposed rule, if finalized, is beyond the scope of this Report, the effect of the proposed rule would be to increase generally the RVUs assigned to the vascular services. Accordingly, since this Report does not consider these proposed changes this Report may understate the effect of the DRA on the vascular services.

3. Use the mean HCPCS code cost for the basis of APC payment instead of the median HCPCS cost for vascular procedures, as has been done on at least one other occasion by CMS[6]

4. Re-assign vascular ultrasound codes to a different APC, while using the mean HCPCS code cost for the basis of APC payment, instead of the median HCPCS cost for vascular procedures.

II. VASCULAR IMAGING HCPCS AND APC ASSIGNMENT

The 25 vascular non-evasive testing HCPCS codes currently map to three APCs in an OPPS environment. These APCs include:

- 0096-Non-Invasive Vascular Studies
- 0266-Level II Diagnostic Ultrasound
- 0267-Level III Diagnostic Ultrasound

The majority of vascular procedures (63%), based on frequency, map to APC 0267. Other imaging specialty HCPCS codes including echocardiogram, computerized axial tomography (CAT/CT), and magnetic resonance imaging (MRI) are found in numerous other APCs, as shown in ***Appendix B***.

A. PFS Reimbursement Loss to Vascular Imaging HCPCS

Figures 1A, 1B, and 1C show the reimbursement reduction for each of the three APCs containing the vascular HCPCS. Vascular ultrasound codes account for close to 100% of the reimbursement reduction to PFS providers in each of the three APCs.

NOTE: The ultrasound HCPCS codes are bolded.

[6] CMS used an amount that approximated mean costs in addressing cochlear implants.

Figure 1A: Reimbursement Reduction to HCPCS Assigned to APC 0096, Non-Invasive Vascular Studies

APC	HCPCS	HCPCS Description	PFS 2006 Non-Facility Total RVU	PFS 2006 National Unadjusted Allowed Amount	OPPS HCPC Median Cost	OPPS APC Median Cost	OPPS APC Payment Rate	DRA Induced Rate Used	PFS Impact from DRA per Procedure	2003 PFS Frequency	DRA Impact on PFS Payment
0096	**Non-Invasive Vascular Studies**										
0096	76820	Umbilical artery echo	1.73	$65.72	$0.00	$95.23	$95.34	$65.72	$0.00	-	-
0096	76821	Middle cerebral artery echo	1.73	$65.72	$0.00	$95.23	$95.34	$65.72	$0.00	-	-
0096	93799	Cardiovascular procedure	0.00	$0.00	$47.57	$95.23	$95.34	$0.00	$0.00	24,621	$0
0096	**93875**	**Extracranial study**	**2.37**	**$90.03**	$112.49	$95.23	**$95.34**	**$90.03**	**$0.00**	**80,668**	$0
0096	**93922**	**Extremity study**	**2.74**	**$104.09**	$64.40	$95.23	**$95.34**	**$95.34**	**-$8.75**	**161,580**	**-$1,413,138**
0096	**93923**	**Extremity study**	**4.11**	**$156.13**	$102.67	$95.23	**$95.34**	**$95.34**	**-$60.79**	**263,682**	**-$16,028,836**
0096	**93924**	**Extremity study**	**4.88**	**$185.38**	$114.73	$95.23	**$95.34**	**$95.34**	**-$90.04**	**48,900**	**-$4,402,862**
0096	**93965**	**Extremity study**	**2.80**	**$106.37**	$96.50	$95.23	**$95.34**	**$95.34**	**-$11.03**	**103,283**	**-$1,138,690**
								All APC 0096 HCPCS			-$22,983,526
								Vascular Ultrasound HCPCS			-$22,983,526
								Percent Vascular Ultrasound			100.0%

Source: Lewin Group analysis of 2005 CMS published data and 2003 publicly available BMAD data.

Figure 1A: Reimbursement Reduction to HCPCS Assigned to APC 0096, Non-Invasive Vascular Studies

APC	HCPCS	HCPCS Description	PFS 2006 Non-Facility Total RVU	PFS 2006 National Unadjusted Allowed Amount	OPPS HCPC Median Cost	OPPS APC Median Cost	OPPS APC Payment Rate	DRA Induced Rate Used	PFS Impact from DRA per Procedure	2003 PFS Frequency	DRA Impact on PFS Payment
0096	Non-Invasive Vascular Studies										
0096	76820	Umbilical artery echo	1.73	$65.72	$0.00	$95.23	$95.34	$65.72	$0.00	-	-
0096	76821	Middle cerebral artery echo	1.73	$65.72	$0.00	$95.23	$95.34	$65.72	$0.00	-	-
0096	93799	Cardiovascular procedure	0.00	$0.00	$47.57	$95.23	$95.34	$0.00	$0.00	24,621	$0
0096	**93875**	**Extracranial study**	**2.37**	**$90.03**	$112.49	$95.23	**$95.34**	**$90.03**	**$0.00**	**80,668**	$0
0096	**93922**	**Extremity study**	**2.74**	**$104.09**	$64.40	$95.23	**$95.34**	**$95.34**	**-$8.75**	**161,580**	**-$1,413,138**
0096	**93923**	**Extremity study**	**4.11**	**$156.13**	$102.67	$95.23	**$95.34**	**$95.34**	**-$60.79**	**263,682**	**-$16,028,836**
0096	**93924**	**Extremity study**	**4.88**	**$185.38**	$114.73	$95.23	**$95.34**	**$95.34**	**-$90.04**	**48,900**	**-$4,402,862**
0096	**93965**	**Extremity study**	**2.80**	**$106.37**	$96.50	$95.23	**$95.34**	**$95.34**	**-$11.03**	**103,283**	**-$1,138,690**
								All APC 0096 HCPCS			-$22,983,526
								Vascular Ultrasound HCPCS			-$22,983,526
								Percent Vascular Ultrasound			100.0%

Source: Lewin Group analysis of 2005 CMS published data and 2003 publicly available BMAD data.

Figure 1B: Reimbursement Reduction to HCPCS Assigned to APC 0266, Level II Diagnostic Ultrasound

APC	HCPCS	HCPCS Description	PFS 2006 Non-Facility Total RVU	PFS 2006 National Unadjusted Allowed Amount	OPPS HCPC Median Cost	OPPS APC Median Cost	OPPS APC Payment Rate	DRA Induced Rate Used	PFS Impact from DRA per Procedure	2003 PFS Frequency	DRA Impact on PFS Payment
0266	**Level II Diagnostic Ultrasound**				$0.00	$0.00					
0266	75946	Intravascular us add-on	0.00	$0.00	$75.32	$94.42	$94.52	$0.00	$0.00	16	$0
0266	76510	Ophth us, b & quant a	2.26	$85.85	$0.00	$94.42	$94.52	$85.85	$0.00	-	-
0266	76511	Ophth us, quant a only	2.11	$80.15	$84.88	$94.42	$94.52	$80.15	$0.00	9,339	$0
0266	76512	Ophth us, b w/non-quant a	1.92	$72.94	$85.87	$94.42	$94.52	$72.94	$0.00	110,964	$0
0266	76513	Echo exam of eye, water bath	1.62	$61.54	$93.95	$94.42	$94.52	$61.54	$0.00	1,987	$0
0266	76519	Echo exam of eye	1.38	$52.42	$74.60	$94.42	$94.52	$52.42	$0.00	1,014,008	$0
0266	76536	Us exam of head and neck	1.50	$56.98	$79.06	$94.42	$94.52	$56.98	$0.00	116,729	$0
0266	76604	Us exam, chest, b-scan	1.38	$52.42	$66.75	$94.42	$94.52	$52.42	$0.00	3,122	$0
0266	76700	Us exam, abdom, complete	2.09	$79.39	$112.39	$94.42	$94.52	$79.39	$0.00	419,709	$0
0266	76705	Echo exam of abdomen	1.50	$56.98	$84.88	$94.42	$94.52	$56.98	$0.00	126,227	$0
0266	76770	Us exam abdo back wall, comp	2.09	$79.39	$94.12	$94.42	$94.52	$79.39	$0.00	350,698	$0
0266	76775	Us exam abdo back wall, lim	1.50	$56.98	$80.52	$94.42	$94.52	$56.98	$0.00	215,236	$0
0266	76778	Us exam kidney transplant	2.09	$79.39	$93.15	$94.42	$94.52	$79.39	$0.00	2,537	$0
0266	76800	Us exam, spinal canal	1.50	$56.98	$68.90	$94.42	$94.52	$56.98	$0.00	4,770	$0
0266	76801	Ob us < 14 wks, single fetus	2.23	$84.71	$75.11	$94.42	$94.52	$84.71	$0.00	954	$0
0266	76805	Ob us >/= 14 wks, sngl fetus	2.23	$84.71	$94.58	$94.42	$94.52	$84.71	$0.00	5,703	$0
0266	76810	Ob us >/= 14 wks, addl fetus	1.27	$48.24	$109.90	$94.42	$94.52	$48.24	$0.00	183	$0
0266	76812	Ob us, detailed, addl fetus	1.46	$55.46	$68.17	$94.42	$94.52	$55.46	$0.00	59	$0
0266	76817	Transvaginal us, obstetric	1.58	$60.02	$66.30	$94.42	$94.52	$60.02	$0.00	1,864	$0
0266	76818	Fetal biophys profile w/nst	1.71	$64.96	$76.31	$94.42	$94.52	$64.96	$0.00	1,122	$0
0266	76819	Fetal biophys profil w/o nst	1.71	$64.96	$75.14	$94.42	$94.52	$64.96	$0.00	1,028	$0
0266	76830	Transvaginal us, non-ob	1.62	$61.54	$78.57	$94.42	$94.52	$61.54	$0.00	162,975	$0
0266	76856	Us exam, pelvic, complete	1.62	$61.54	$93.44	$94.42	$94.52	$61.54	$0.00	261,206	$0
0266	76870	Us exam, scrotum	1.62	$61.54	$83.93	$94.42	$94.52	$61.54	$0.00	28,913	$0
0266	76872	Us, transrectal	2.13	$80.91	$87.83	$94.42	$94.52	$80.91	$0.00	237,278	$0
0266	76873	Echograp trans r, pros study	2.27	$86.23	$101.38	$94.42	$94.52	$86.23	$0.00	11,269	$0
0266	76880	Us exam, extremity	1.50	$56.98	$75.88	$94.42	$94.52	$56.98	$0.00	44,351	$0
0266	76886	Us exam infant hips, static	1.50	$56.98	$75.33	$94.42	$94.52	$56.98	$0.00	14	$0
0266	76975	GI endoscopic ultrasound	1.62	$61.54	$115.13	$94.42	$94.52	$61.54	$0.00	146	$0
0266	76986	Ultrasound guide intraoper	2.77	$105.23	$112.51	$94.42	$94.52	$94.52	-$10.71	1,700	-$18,194
0266	**93888**	**Intracranial study**	**4.29**	**$162.97**	$65.47	$94.42	**$94.52**	**$94.52**	**-$68.45**	**9,592**	**-$656,538**
0266	**93890**	**Tcd, vasoreactivity study**	**4.90**	**$186.14**	$0.00	$94.42	**$94.52**	**$94.52**	**-$91.62**	-	-
0266	**93892**	**Tcd, emboli detect w/o inj**	**5.10**	**$193.74**	$0.00	$94.42	**$94.52**	**$94.52**	**-$99.22**	-	-
0266	**93893**	**Tcd, emboli detect w/inj**	**4.97**	**$188.80**	$0.00	$94.42	**$94.52**	**$94.52**	**-$94.28**	-	-
0266	**93926**	**Lower extremity study**	**4.16**	**$158.03**	$102.11	$94.42	**$94.52**	**$94.52**	**-$63.51**	**66,411**	**-$4,217,598**
0266	**93931**	**Upper extremity study**	**3.63**	**$137.89**	$82.60	$94.42	**$94.52**	**$94.52**	**-$43.37**	**8,344**	**-$361,896**
0266	**93971**	**Extremity study**	**3.72**	**$141.31**	$106.77	$94.42	**$94.52**	**$94.52**	**-$46.79**	**175,718**	**-$8,222,460**
0266	**93978**	**Vascular study**	**4.67**	**$177.40**	$125.53	$94.42	**$94.52**	**$94.52**	**-$82.88**	**136,258**	**-$11,293,284**
0266	**93979**	**Vascular study**	**3.31**	**$125.74**	$93.04	$94.42	**$94.52**	**$94.52**	**-$31.22**	**27,788**	**-$867,503**
0266	**93981**	**Penile vascular study**	**3.05**	**$115.86**	$68.88	$94.42	**$94.52**	**$94.52**	**-$21.34**	**210**	**-$4,482**
0266	**93990**	**Doppler flow testing**	**4.14**	**$157.27**	$86.87	$94.42	**$94.52**	**$94.52**	**-$62.75**	**7,735**	**-$485,326**
								All APC 0096 HCPCS			-$26,127,282
								Vascular Ultrasound HCPCS			-$26,109,088
								Percent Vascular Ultrasound			99.9%

Source: Lewin Group analysis of 2005 CMS published data and 2003 publicly available BMAD data.

Figure 1C: Reimbursement Reduction to HCPCS Assigned to APC 0267, Level III Diagnostic Ultrasound

APC	HCPCS	HCPCS Description	PFS 2006 Non-Facility Total RVU	PFS 2006 National Unadjusted Allowed Amount	OPPS HCPC Median Cost	OPPS APC Median Cost	OPPS APC Payment Rate	DRA Induced Rate Used	PFS Impact from DRA per Procedure	2003 PFS Frequency	DRA Impact on PFS Payment
0267	**Level III Diagnostic Ultrasound**										
0267	76831	Echo exam, uterus	1.62	$61.54	$152.74	$151.84	$152.01	$61.54	$0.00	4,123	$0
0267	**93980**	**Penile vascular study**	**2.79**	**$105.99**	$129.61	$151.84	**$152.01**	**$105.99**	**$0.00**	**5,066**	**$0**
0267	**93882**	**Extracranial study**	**3.59**	**$136.38**	$110.76	$151.84	**$152.01**	**$136.38**	**$0.00**	**24,918**	**$0**
0267	76811	Ob us, detailed, sngl fetus	3.97	$150.81	$110.33	$151.84	$152.01	$150.81	$0.00	1,461	$0
0267	G0365	Vessel mapping hemo access	4.14	$157.27	$0.00	$151.84	$152.01	$152.01	-$5.26	-	-
0267	**93976**	**Vascular study**	**4.24**	**$161.07**	$106.70	$151.84	**$152.01**	**$152.01**	**-$9.06**	**14,024**	**-$127,011**
0267	75945	Intravascular us	4.81	$182.72	$110.97	$151.84	$152.01	$152.01	-$30.71	64	-$1,965
0267	**93970**	**Extremity study**	**5.43**	**$206.27**	$151.13	$151.84	**$152.01**	**$152.01**	**-$54.26**	**257,720**	**-$13,984,435**
0267	**93930**	**Upper extremity study**	**5.58**	**$211.97**	$138.04	$151.84	**$152.01**	**$152.01**	**-$59.96**	**7,825**	**-$469,159**
0267	**93880**	**Extracranial study**	**5.72**	**$217.29**	$156.20	$151.84	**$152.01**	**$152.01**	**-$65.28**	**1,188,176**	**-$77,562,314**
0267	**93886**	**Intracranial study**	**6.78**	**$257.56**	$124.27	$151.84	**$152.01**	**$152.01**	**-$105.55**	**52,796**	**-$5,572,314**
0267	**93925**	**Lower extremity study**	**6.95**	**$264.01**	$140.75	$151.84	**$152.01**	**$152.01**	**-$112.00**	**254,864**	**-$28,545,564**
0267	**93975**	**Vascular study**	**7.48**	**$284.15**	$143.51	$151.84	**$152.01**	**$152.01**	**-$132.14**	**52,634**	**-$6,954,806**
0267	36002	Pseudoaneurysm injection trt			$491.10	$151.84	$152.01	$152.01	$0.00	100	$0
								All APC 0096 HCPCS			-$133,217,570
								Vascular Ultrasound HCPCS			-$133,215,604
								Percent Vascular Ultrasound			100.0%

Source: Lewin Group analysis of 2005 CMS published data and 2003 publicly available BMAD data.

Lewin calculated the potential reimbursement loss as a result of the DRA to the 252 imaging HCPCS codes spanning 19 APCs based on the DRA mandate and the frequency of these HCPCS codes performed in a PFS environment. Twenty-five vascular codes in three APCs account for almost 24% ($182M) of the Lewin estimated over $770M reduction in reimbursement for imaging services in a PFS environment. This finding reveals that 24% of the effect of DRA is attributed to just 25 of 252 codes or less than 10% of the affected codes. Significantly, the $770M impact that we identify for the DRA is approximately $220M more than the Congressional Budget Office estimates of the DRA impact, even though the CBO estimate considered the various imaging components of the DRA, and not just the HOPD ceiling component of the DRA, the element of the DRA that we examined. This suggests that significant relief can be given to rescue these procedures without preventing the level of savings that Congress intended.

Our analysis is consistent with another study that has been undertaken. The study "Overview of DRA Impact on Vascular Ultrasound", conducted by the Society of Diagnostic Medical Sonography and the Society of Vascular Ultrasound estimated a $160M loss for the top 20 vascular ultrasound codes. Using the Lewin methodology and BMAD data as detailed in *Appendix C*, the same 20 vascular ultrasound codes result in a $159M loss.

B. Differences in OPPS Payment Rate and PFS Payment Rate

The reimbursement differences between the OPPS and PFS payment rates are based on the calculation methodology for the OPPS which is based on a median cost of the APC derived from a RCC calculation from the Medicare cost report for each hospital. The PFS payment rate is based on the RVU assigned to each individual HCPCS code multiplied by a conversion factor as determined by CMS.

When we compare the PFS RVUs of HCPCS with their median costs within an APC, we find a wide variation in RVU weights. Sixteen of the twenty-five vascular codes fall within a range of 35 imaging HCPCS when arranged by median cost (please note, again, that there are 252 imaging codes overall). We find that the HCPCS median cost for these 35 imaging procedures ranges from $96.50 per procedure to $156.20 per procedure. Within these 35 codes, the average median cost for non-vascular testing HCPCS codes is just over $118 (un-weighted) while the average RVU for such codes equals 2.57. The vascular ultrasound codes within this 35 code range average an RVU of 4.88, almost double that of the non-vascular testing codes. This shows that for these codes, although the average HCPCS codes median costs are within an approximate $55 range, the PFS methodology provides a $235.90 range of payment from $48.24 to $284.15.

Comparing the ultrasound codes to the non-vascular ultrasound codes within this 35 code range shows that the average PFS vascular payment within this range is $185.35, while the average non-vascular ultrasound (un-weighted) PFS payment is $105.14.

Since there is an average $80 difference in payment between the vascular services and the non-vascular ultrasound codes, a similar difference in HCPCS code median costs would be expected.

However, when we analyze the HCPCS within APC median cost data, the average median cost for the vascular ultrasound procedures is $124.94, only slightly higher than the non-vascular ultrasound median cost of $118.24. This would suggest that if RBRVS is at all accurate, the OPPS does not adequately track vascular ultrasound relative values.

In addition, as shown in ***Figure*** 2, under the DRA, the greatest potential PFS loss based on the frequency of each HCPCS code in 2003 is found in vascular codes. Vascular procedures represent approximately 46% of the imaging code frequency; however, the PFS loss to the vascular services is more than 99% of the total PFS loss in these codes.

Figure 2: Imaging Codes Arrayed by HCPC Median Cost

APC	HCPCS	HCPCS Description	PFS 2006 Non-Facility Total RVU	PFS 2006 National Unadjusted Allowed Amount	APC HCPC Median Cost	APC Payment Rate	DRA Induced Rate Used	PFS Impact from DRA per Procedure	2003 PFS Frequency	DRA Impact on PFS Payment
0096	**93965**	**Extremity study**	**2.8**	**$106.37**	**$96.50**	**$95.34**	**$95.34**	**-$11.03**	**103,283**	**-$1,138,690**
0268	76945	Echo guide, villus sampling	1.61	$61.16	$99.24	$62.25	$61.16	$0.00	33	$0
0340	15852	Dressing change not for burn	NA		$99.46	$36.52	$36.52	$36.52		$0
0671	93320	Doppler echo exam, heart	1.83	$69.52	$99.65	$99.76	$69.52	$0.00	2,646,971	$0
0266	76873	Echograp trans r, pros study	2.27	$86.23	$101.38	$94.52	$86.23	$0.00	11,269	$0
0266	**93926**	**Lower extremity study**	**4.16**	**$158.03**	**$102.11**	**$94.52**	**$94.52**	**-$63.51**	**66,411**	**-$4,217,598**
0096	**93923**	**Extremity study**	**4.11**	**$156.13**	**$102.67**	**$95.34**	**$95.34**	**-$60.79**	**263,682**	**-$16,028,836**
0282	76497	Ct procedure	0		$103.56	$94.82	$94.82	$94.82	57	$5,405
0671	76825	Echo exam of fetal heart	2.09	$79.39	$104.03	$99.76	$79.39	$0.00	271	$0
0267	**93976**	**Vascular study**	**4.24**	**$161.07**	**$106.70**	**$152.01**	**$152.01**	**-$9.06**	**14,024**	**-$127,011**
0266	**93971**	**Extremity study**	**3.72**	**$141.31**	**$106.77**	**$94.52**	**$94.52**	**-$46.79**	**175,718**	**-$8,222,460**
0266	76810	Ob us >/= 14 wks, addl fetus	1.27	$48.24	$109.90	$94.52	$48.24	$0.00	183	$0
0340	40804	Removal, foreign body, mouth	NA		$109.96	$36.52	$36.52	$36.52		$0
0267	76811	Ob us, detailed, sngl fetus	3.97	$150.81	$110.33	$152.01	$150.81	$0.00	1,461	$0
0267	**93882**	**Extracranial study**	**3.59**	**$136.38**	**$110.76**	**$152.01**	**$136.38**	**$0.00**	**24,918**	**$0**
0267	75945	Intravascular us	4.81	$182.72	$110.97	$152.01	$152.01	-$30.71	64	-$1,965
0266	76700	Us exam, abdom, complete	2.09	$79.39	$112.39	$94.52	$79.39	$0.00	419,709	$0
0096	**93875**	**Extracranial study**	**2.37**	**$90.03**	**$112.49**	**$95.34**	**$90.03**	**$0.00**	**80,668**	**$0**
0266	76986	Ultrasound guide intraoper	2.77	$105.23	$112.51	$94.52	$94.52	-$10.71	1,700	-$18,194
0282	76370	Ct scan for therapy guide	3.12	$118.52	$114.50	$94.82	$94.82	-$23.70	46,496	-$1,101,990
0697	93308	Echo exam of heart	2.08	$79.01	$114.62	$89.99	$79.01	$0.00	18,822	$0
0096	**93924**	**Extremity study**	**4.88**	**$185.38**	**$114.73**	**$95.34**	**$95.34**	**-$90.04**	**48,900**	**-$4,402,862**
0266	76975	GI endoscopic ultrasound	1.62	$61.54	$115.13	$94.52	$61.54	$0.00	146	$0
0268	76940	Us guide, tissue ablation	1.81	$68.76	$120.71	$62.25	$62.25	-$6.51		$0
0267	**93886**	**Intracranial study**	**6.78**	**$257.56**	**$124.27**	**$152.01**	**$152.01**	**-$105.55**	**52,796**	**-$5,572,314**
0266	**93978**	**Vascular study**	**4.67**	**$177.40**	**$125.53**	**$94.52**	**$94.52**	**-$82.88**	**136,258**	**-$11,293,284**
0267	**93980**	**Penile vascular study**	**2.79**	**$105.99**	**$129.61**	**$152.01**	**$105.99**	**$0.00**	**5,066**	**$0**
0268	76936	Echo guide for artery repair	6.65	$252.62	$135.76	$62.25	$62.25	-$190.37	288	-$54,730
0267	**93930**	**Upper extremity study**	**5.58**	**$211.97**	**$138.04**	**$152.01**	**$152.01**	**-$59.96**	**7,825**	**-$469,159**
0697	93304	Echo transthoracic	2.08	$79.01	$138.19	$89.99	$79.01	$0.00	227	$0
0267	**93925**	**Lower extremity study**	**6.95**	**$264.01**	**$140.75**	**$152.01**	**$152.01**	**-$112.00**	**254,864**	**-$28,545,564**
0267	**93975**	**Vascular study**	**7.48**	**$284.15**	**$143.51**	**$152.01**	**$152.01**	**-$132.14**	**52,634**	**-$6,954,806**
0267	**93970**	**Extremity study**	**5.43**	**$206.27**	**$151.13**	**$152.01**	**$152.01**	**-$54.26**	**257,720**	**-$13,984,435**
0267	76831	Echo exam, uterus	1.62	$61.54	$152.74	$152.01	$61.54	$0.00	4,123	$0
0267	**93880**	**Extracranial study**	**5.72**	**$217.29**	**$156.20**	**$152.01**	**$152.01**	**-$65.28**	**1,188,176**	**-$77,562,314**
		Total	3.54	138.84	117.91				5,884,755	-179,690,809
		Vascular Ultrasound	4.88	185.35	125.94				2,732,938	-178,519,334
		Non Vascular Ultrasound	2.57	105.14	118.24				3,151,818	-1,171,475
		Percent Vascular Ultrasound							46.44%	99.35%
		Percent Non Vascular Ultrasound							53.56%	0.65%

Source: Lewin Group analysis of 2005 CMS published data and 2003 publicly available BMAD data.

The same is true for the inverse calculation. In looking at the 252 imaging codes ranked by RVU, 24 of the 25 vascular ultrasound codes fall within 58 HCPCS codes when arrayed by RVU. Within this HCPCS code sample, the RVUs range from 2.37 to 6.95. Comparing the difference between the PFS payment and the OPPS payment, weighted by frequency, we find that the set of 58 HCPCS codes have a $25.16 difference between the PFS payment and the OPPS payment. The vascular codes produce a weighted difference of $58.82 and the non-vascular ultrasound codes (primarily CT) have a $7.49 dollar weighted difference between PFS and OPPS reimbursement amounts. Un-weighted, we see a similar trend in that the vascular codes on average pay $44.56 less in an OPPS environment than a PFS environment and non-vascular ultrasound codes on average pay $14.56 less in an OPPS environment. The primary reason this $14.56 decreases to a $7.40 difference is due the certain codes paying more, not less, in the OPPS environment.

Figure 3 shows the differences in payment for 24 of 25 the vascular codes, and the array of similar imaging codes, based on RVU. Only 3 of the 24 (12.5% of codes, but only 3.8% of vascular HCPCS code frequency) vascular codes are reimbursed at a higher rate in the OPPS environment compared to the PFS environment, while 10 of the remaining 34 (29.4%) codes including echocardiogram and CT are reimbursed at a higher rate in the OPPS environment.

Figure 3: Imaging Codes Arrayed by PFS 2006 Non-Facility Total RVU

APC	HCPCS	HCPCS Description	PFS 2006 Non-Facility Total RVU	PFS 2006 National Unadjusted Allowed Amount	OPPS HCPC Median Cost	OPPS APC Payment Rate	DRA Induced Rate Used	PFS Impact from DRA per Procedure	OPPS "Single" Frequency (for weight)	2003 PFS Frequency	DRA Impact on PFS Payment	Difference between PFS and OPPS	Weighted Difference
0096	**93875**	**Extracranial study**	**2.37**	**$90.03**	**$112.49**	**$96.34**	**$90.03**	**$0.00**	**19,241**	**80,668**	**$0**	**-$6.31**	**-$630,477**
0096	**93922**	**Extremity study**	**2.74**	**$104.09**	**$64.40**	**$96.34**	**$96.34**	**-$8.76**	**89,329**	**161,680**	**-$1,413,138**	**$8.76**	**$2,194,387**
0266	76986	Ultrasound guide intraoper	2.77	$105.23	$112.51	$94.52	$94.52	-$10.71	253	1,700	-$18,194	$10.71	$20,902
0267	**93980**	**Penile vascular study**	**2.79**	**$106.99**	**$129.61**	**$162.01**	**$106.99**	**$0.00**	**224**	**6,066**	**$0**	**-$46.02**	**-$243,449**
0096	**93965**	**Extremity study**	**2.80**	**$106.37**	**$96.50**	**$96.34**	**$96.34**	**-$11.03**	**32,698**	**103,283**	**-$1,138,690**	**$11.03**	**$1,498,083**
0268	76942	Echo guide for biopsy	2.92	$110.92	$95.56	$62.25	$62.25	-$48.67	70,615	237,104	-$11,540,682	$48.67	$14,977,761
0282	76071	Ct bone density, penpheral	3.01	$114.34	$59.74	$94.82	$94.82	-$19.52	846	933	-$18,214	$19.52	$34,730
0266	**93981**	**Penile vascular study**	**3.06**	**$116.86**	**$68.88**	**$94.62**	**$94.62**	**-$21.34**	**24**	**210**	**-$4,482**	**$21.34**	**$4,994**
0282	76370	Ct scan for therapy guide	3.12	$118.52	$114.50	$94.82	$94.82	-$23.70	105,200	46,496	-$1,101,990	$23.70	$3,595,335
0697	93325	Doppler color flow add-on	3.12	$118.52	$89.70	$89.99	$89.99	-$28.53	701,799	2,626,759	-$74,944,047	$28.53	$94,967,074
0266	**93979**	**Vascular study**	**3.31**	**$125.74**	**$93.04**	**$94.62**	**$94.62**	**-$31.22**	**6,179**	**27,788**	**-$867,503**	**$31.22**	**$1,060,403**
0340	76376	3d render w/o postprocess	3.51	$133.34		$36.52	$36.52	-$96.82				$96.82	
0267	**93882**	**Extracranial study**	**3.59**	**$136.38**	**$110.76**	**$162.01**	**$136.38**	**$0.00**	**5,432**	**24,918**	**$0**	**-$15.63**	**-$474,518**
0266	**93931**	**Upper extremity study**	**3.63**	**$137.89**	**$82.60**	**$94.62**	**$94.62**	**-$43.37**	**11,964**	**8,344**	**-$361,896**	**$43.37**	**$880,396**
0282	76380	CAT scan follow-up study	3.69	$140.17	$95.68	$94.82	$94.82	-$45.35	44,755	13,733	-$622,845	$45.35	$2,652,657
0266	**93971**	**Extremity study**	**3.72**	**$141.31**	**$106.77**	**$94.62**	**$94.62**	**-$46.79**	**488,641**	**176,718**	**-$8,222,460**	**$46.79**	**$31,083,004**
0282	76377	3d rendering w/postprocess	3.74	$142.07		$94.82	$94.82	-$47.25				$47.25	
0267	76811	Ob us, detailed, sngl fetus	3.97	$150.81	$110.33	$152.01	$150.81	$0.00	1,653	1,461	$0	-$1.20	-$3,736
0270	93312	Echo transesophageal	4.08	$154.99	$353.69	$353.31	$154.99	$0.00	12,402	3,771	$0	-$198.32	-$3,207,446
0269	93307	Echo exam of heart	4.10	$155.75	$184.33	$189.01	$155.75	$0.00	822,992	2,583,430	$0	-$33.26	-$113,301,837
0269	93303	Echo transthoracic	4.10	$155.75	$212.89	$189.01	$155.75	$0.00	2,514	1,897	$0	-$33.26	-$146,715
0096	**93923**	**Extremity study**	**4.11**	**$156.13**	**$102.67**	**$96.34**	**$96.34**	**-$60.79**	**196,024**	**263,682**	**-$16,028,836**	**$60.79**	**$27,884,077**
0267	G0365	Vessel mapping hemo access	4.14	$157.27		$152.01	$152.01	-$5.26				$5.26	
0266	**93990**	**Doppler flow testing**	**4.14**	**$157.27**	**$86.87**	**$94.62**	**$94.62**	**-$62.76**	**6,148**	**7,736**	**-$485,326**	**$62.76**	**$808,364**
0266	**93926**	**Lower extremity study**	**4.16**	**$158.03**	**$102.11**	**$94.62**	**$94.62**	**-$63.61**	**47,263**	**66,411**	**-$4,217,598**	**$63.61**	**$7,219,177**
0267	**93978**	**Vascular study**	**4.24**	**$161.07**	**$106.70**	**$162.01**	**$162.01**	**-$9.06**	**22,219**	**14,024**	**-$127,011**	**$9.06**	**$328,248**
0266	**93888**	**Intracranial study**	**4.29**	**$162.97**	**$65.47**	**$94.62**	**$94.62**	**-$68.46**	**4,620**	**9,592**	**-$656,638**	**$68.46**	**$972,760**
0266	**93978**	**Vascular study**	**4.67**	**$177.40**	**$125.63**	**$94.62**	**$94.62**	**-$82.88**	**24,372**	**136,268**	**-$11,293,284**	**$82.88**	**$13,313,278**
0267	75945	Intravascular us	4.81	$182.72	$110.97	$152.01	$152.01	-$30.71	1,145	64	-$1,965	$30.71	$37,128
0096	**93924**	**Extremity study**	**4.88**	**$185.38**	**$114.73**	**$96.34**	**$96.34**	**-$90.04**	**36,236**	**48,900**	**-$4,402,862**	**$90.04**	**$7,846,593**
0266	**93890**	**Tcd, vasoreactivity study**	**4.90**	**$186.14**		**$94.62**	**$94.62**	**-$91.62**				$91.62	
0266	**93893**	**Tcd, emboli detect w/inj**	**4.97**	**$188.80**		**$94.62**	**$94.62**	**-$94.28**				$94.28	
0332	70486	Ct maxillofacial w/o dye	4.98	$189.18	$172.70	$188.10	$188.10	-$1.08	175,585	89,670	-$96,641	$1.08	$285,878
0332	70480	Ct orbit/ear/fossa w/o dye	4.98	$189.18	$180.17	$188.10	$188.10	-$1.08	32,765	13,175	-$14,199	$1.08	$49,511
0332	70450	Ct head/brain w/o dye	4.98	$189.18	$185.15	$188.10	$188.10	-$1.08	1,472,634	150,474	-$162,173	$1.08	$1,749,305
0332	70490	Ct soft tissue neck w/o dye	4.98	$189.18	$187.34	$188.10	$188.10	-$1.08	15,947	9,983	-$10,759	$1.08	$27,946
0266	**93892**	**Tcd, emboli detect w/o inj**	**5.10**	**$193.74**		**$94.62**	**$94.62**	**-$99.22**				$99.22	
0332	73200	Ct upper extremity w/o dye	5.22	$198.29	$186.68	$188.10	$188.10	-$10.19	13,420	7,450	-$75,946	$10.19	$212,759
0332	73700	Ct lower extremity w/o dye	5.22	$198.29	$189.20	$188.10	$188.10	-$10.19	34,667	13,679	-$139,449	$10.19	$492,870
0267	**93970**	**Extremity study**	**5.43**	**$206.27**	**$161.13**	**$162.01**	**$162.01**	**-$54.26**	**242,432**	**257,720**	**-$13,984,436**	**$54.26**	**$27,139,310**
0267	**93930**	**Upper extremity study**	**5.58**	**$211.97**	**$138.04**	**$162.01**	**$162.01**	**-$69.96**	**4,666**	**7,826**	**-$469,169**	**$69.96**	**$748,274**
0267	**93880**	**Extracranial study**	**5.72**	**$217.29**	**$166.20**	**$162.01**	**$162.01**	**-$66.28**	**763,007**	**1,188,176**	**-$77,562,314**	**$66.28**	**$126,717,482**
0268	76965	Echo guidance radiotherapy	5.88	$223.37	$49.11	$62.25	$62.25	-$161.12	1,944	2,438	-$392,802	$161.12	$706,013
0283	70487	Ct maxillofacial w/dye	5.98	$227.17	$2.36	$255.43	$227.17	$0.00	3,424	1,478	$0	-$28.26	-$138,540
0283	70460	Ct head/brain w/dye	5.98	$227.17	$221.65	$255.43	$227.17	$0.00	16,340	9,927	$0	-$28.26	-$742,430
0283	70481	Ct orbit/ear/fossa w/dye	5.98	$227.17	$228.72	$255.43	$227.17	$0.00	4,231	1,882	$0	-$28.26	-$172,782
0283	70491	Ct soft tissue neck w/dye	5.98	$227.17	$249.82	$255.43	$227.17	$0.00	77,584	40,721	$0	-$28.26	-$3,343,861
0332	74150	Ct abdomen w/o dye	5.98	$227.17	$196.24	$188.10	$188.10	-$39.07	320,563	143,503	-$5,605,981	$39.07	$18,128,854
0283	73201	Ct upper extremity w/dye	6.24	$237.04	$219.66	$255.43	$237.04	$0.00	927	647	$0	-$18.39	-$28,934
0283	73701	Ct lower extremity w/dye	6.24	$237.04	$240.60	$255.43	$237.04	$0.00	3,459	1,014	$0	-$18.39	-$82,240
0332	72192	Ct pelvis w/o dye	6.24	$237.04	$187.22	$188.10	$188.10	-$48.94	458,356	130,708	-$6,397,111	$48.94	$28,829,970
0332	71250	Ct thorax w/o dye	6.24	$237.04	$192.19	$188.10	$188.10	-$48.94	348,177	181,061	-$8,861,463	$48.94	$25,901,942
0332	72128	Ct chest spine w/o dye	6.24	$237.04	$215.41	$188.10	$188.10	-$48.94	16,815	6,372	-$311,858	$48.94	$1,134,818
0332	72125	Ct neck spine w/o dye	6.24	$237.04	$219.16	$188.10	$188.10	-$48.94	98,392	16,604	-$812,633	$48.94	$5,628,134
0332	72131	Ct lumbar spine w/o dye	6.24	$237.04	$222.25	$188.10	$188.10	-$48.94	80,781	49,800	-$2,437,287	$48.94	$6,390,871
0268	76936	Echo guide for artery repair	6.65	$252.62	$135.76	$62.25	$62.25	-$190.37	795	288	-$54,730	$190.37	$206,072
0267	**93886**	**Intracranial study**	**6.78**	**$257.56**	**$124.27**	**$162.01**	**$162.01**	**-$106.56**	**7,329**	**62,796**	**-$6,672,314**	**$106.56**	**$6,346,866**
0267	**93926**	**Lower extremity study**	**6.96**	**$264.01**	**$140.76**	**$162.01**	**$162.01**	**-$112.00**	**84,804**	**264,864**	**-$28,545,564**	**$112.00**	**$38,043,677**
								All	7,023,611	9,283,767		$31.31	$377,701,118
								Vascular	2,077,483	2,887,818		$41.55	$292,030,752
								Non-Vascular	4,940,980	6,388,215		$14.56	$84,862,011
								Average Weighted Difference			All		$23.16
											Vascular		$21.09
											Non-Vascular		$22.62

Source: Lewin Group analysis of 2005 CMS published data and 2003 publicly available BMAD data.

As the above data show, the DRA causes disproportionate losses for vascular service providers.

APPENDIX A: VASCULAR ULTRASOUND SERVICES HCPCS

APC	HCPCS	HCPCS Description
0096	**Non-Invasive Vascular Studies**	
0096	93875	Extracranial study
0096	93922	Extremity study
0096	93923	Extremity study
0096	93924	Extremity study
0096	93965	Extremity study
0266	**Level II Diagnostic Ultrasound**	
0266	93888	Intracranial study
0266	93890	Tcd, vasoreactivity study
0266	93892	Tcd, emboli detect w/o inj
0266	93893	Tcd, emboli detect w/inj
0266	93926	Lower extremity study
0266	93931	Upper extremity study
0266	93971	Extremity study
0266	93978	Vascular study
0266	93979	Vascular study
0266	93981	Penile vascular study
0266	93990	Doppler flow testing
0267	**Level III Diagnostic Ultrasound**	
0267	93980	Penile vascular study
0267	93882	Extracranial study
0267	93976	Vascular study
0267	93970	Extremity study
0267	93930	Upper extremity study
0267	93880	Extracranial study
0267	93886	Intracranial study
0267	93925	Lower extremity study
0267	93975	Vascular study

APPENDIX B: GLOBAL IMAGING HCPCS CODES

APC	HCPCS	HCPCS Description
Non-Invasive Vascular Studies		
0096	76820	Umbilical artery echo
0096	76821	Middle cerebral artery echo
0096	93799	Cardiovascular procedure
0096	93875	Extracranial study
0096	93922	Extremity study
0096	93923	Extremity study
0096	93924	Extremity study
0096	93965	Extremity study
Level I Diagnostic Ultrasound		
0265	76506	Echo exam of head
0265	76516	Echo exam of eye
0265	76529	Echo exam of eye
0265	76645	Us exam, breast(s)
0265	76802	Ob us < 14 wks, addÆl fetus
0265	76815	Ob us, limited, fetus(s)
0265	76816	Ob us, follow-up, per fetus
0265	76857	Us exam, pelvic, limited
0265	76885	Us exam infant hips, dynamic
0265	76970	Ultrasound exam follow-up
0265	76999	Echo examination procedure
Level II Diagnostic Ultrasound		
0266	75946	Intravascular us add-on
0266	76510	Ophth us, b & quant a
0266	76511	Ophth us, quant a only
0266	76512	Ophth us, b w/non-quant a
0266	76513	Echo exam of eye, water bath
0266	76519	Echo exam of eye
0266	76536	Us exam of head and neck
0266	76604	Us exam, chest, b-scan
0266	76700	Us exam, abdom, complete
0266	76705	Echo exam of abdomen
0266	76770	Us exam abdo back wall, comp
0266	76775	Us exam abdo back wall, lim
0266	76778	Us exam kidney transplant
0266	76800	Us exam, spinal canal
0266	76801	Ob us < 14 wks, single fetus
0266	76805	Ob us >/= 14 wks, sngl fetus
0266	76810	Ob us >/= 14 wks, addl fetus
0266	76812	Ob us, detailed, addl fetus
0266	76817	Transvaginal us, obstetric
0266	76818	Fetal biophys profile w/nst
0266	76819	Fetal biophys profil w/o nst

0266	76830	Transvaginal us, non-ob
0266	76856	Us exam, pelvic, complete
0266	76870	Us exam, scrotum
0266	76872	Us, transrectal
0266	76873	Echograp trans r, pros study
0266	76880	Us exam, extremity
0266	76886	Us exam infant hips, static
0266	76975	GI endoscopic ultrasound
0266	76986	Ultrasound guide intraoper
0266	93888	Intracranial study
0266	93890	Tcd, vasoreactivity study
0266	93892	Tcd, emboli detect w/o inj
0266	93893	Tcd, emboli detect w/inj
0266	93926	Lower extremity study
0266	93931	Upper extremity study
0266	93971	Extremity study
0266	93978	Vascular study
0266	93979	Vascular study
0266	93981	Penile vascular study
0266	93990	Doppler flow testing
Level III Diagnostic Ultrasound		
0267	G0365	Vessel mapping hemo access
0267	36002	Pseudoaneurysm injection trt
0267	75945	Intravascular us
0267	76811	Ob us, detailed, sngl fetus
0267	76831	Echo exam, uterus
0267	93880	Extracranial study
0267	93882	Extracranial study
0267	93886	Intracranial study
0267	93925	Lower extremity study
0267	93930	Upper extremity study
0267	93970	Extremity study
0267	93975	Vascular study
0267	93976	Vascular study
0267	93980	Penile vascular study
Ultrasound Guidance Procedures		
0268	76930	Echo guide, cardiocentesis
0268	76932	Echo guide for heart biopsy
0268	76936	Echo guide for artery repair
0268	76940	Us guide, tissue ablation
0268	76941	Echo guide for transfusion
0268	76942	Echo guide for biopsy
0268	76945	Echo guide, villus sampling
0268	76946	Echo guide for amniocentesis
0268	76948	Echo guide, ova aspiration
0268	76950	Echo guidance radiotherapy

0268	76965	Echo guidance radiotherapy
Level III Echocardiogram Except Transesophageal		
0269	93303	Echo transthoracic
0269	93307	Echo exam of heart
0269	93350	Echo transthoracic
Transesophageal Echocardiogram		
0270	93312	Echo transesophageal
0270	93313	Echo transesophageal
0270	93315	Echo transesophageal
0270	93316	Echo transesophageal
0270	93318	Echo transesophageal intraop
Miscellaneous Computerized Axial Tomography		
0282	0151T	Ct Heart Funct Add-On
0282	76071	Ct bone density, peripheral
0282	76370	Ct scan for therapy guide
0282	76377	3d rendering w/postprocess
0282	76380	CAT scan follow-up study
0282	76497	Ct procedure
Computerized Axial Tomography with Contrast Material		
0283	70460	Ct head/brain w/dye
0283	70481	Ct orbit/ear/fossa w/dye
0283	70487	Ct maxillofacial w/dye
0283	70491	Ct soft tissue neck w/dye
0283	71260	Ct thorax w/dye
0283	72126	Ct neck spine w/dye
0283	72129	Ct chest spine w/dye
0283	72132	Ct lumbar spine w/dye
0283	72193	Ct pelvis w/dye
0283	73201	Ct upper extremity w/dye
0283	73701	Ct lower extremity w/dye
0283	74160	Ct abdomen w/dye
0283	76355	Ct scan for localization
0283	76360	Ct scan for needle biopsy
Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contras		
0284	C8900	MRA w/cont, abd
0284	C8903	MRI w/cont, breast, uni
0284	C8906	MRI w/cont, breast, bi
0284	C8909	MRA w/cont, chest
0284	C8912	MRA w/cont, lwr ext
0284	C8918	MRA w/cont, pelvis
0284	70542	Mri orbit/face/neck w/dye
0284	70545	Mr angiography head w/dye
0284	70548	Mr angiography neck w/dye

0284	70552	Mri brain w/dye
0284	70558	Mri brain w/dye
0284	71551	Mri chest w/dye
0284	72142	Mri neck spine w/dye
0284	72147	Mri chest spine w/dye
0284	72149	Mri lumbar spine w/dye
0284	72196	Mri pelvis w/dye
0284	73219	Mri upper extremity w/dye
0284	73222	Mri joint upr extrem w/dye
0284	73719	Mri lower extremity w/dye
0284	73722	Mri joint of lwr extr w/dye
0284	74182	Mri abdomen w/dye
0284	75553	Heart mri for morph w/dye
Computerized Axial Tomography and Computerized Angiography without Contras		
0332	70450	Ct head/brain w/o dye
0332	70480	Ct orbit/ear/fossa w/o dye
0332	70486	Ct maxillofacial w/o dye
0332	70490	Ct soft tissue neck w/o dye
0332	71250	Ct thorax w/o dye
0332	72125	Ct neck spine w/o dye
0332	72128	Ct chest spine w/o dye
0332	72131	Ct lumbar spine w/o dye
0332	72192	Ct pelvis w/o dye
0332	73200	Ct upper extremity w/o dye
0332	73700	Ct lower extremity w/o dye
0332	74150	Ct abdomen w/o dye
Computerized Axial Tomography and Computerized Angiography without Contrast		
0333	0067T	Ct colonography;dx
0333	70470	Ct head/brain w/o & w/dye
0333	70482	Ct orbit/ear/fossa w/o&w/dye
0333	70488	Ct maxillofacial w/o & w/dye
0333	70492	Ct sft tsue nck w/o & w/dye
0333	71270	Ct thorax w/o & w/dye
0333	72127	Ct neck spine w/o & w/dye
0333	72130	Ct chest spine w/o & w/dye
0333	72133	Ct lumbar spine w/o & w/dye
0333	72194	Ct pelvis w/o & w/dye
0333	73202	Ct uppr extremity w/o&w/dye
0333	73702	Ct lwr extremity w/o&w/dye
0333	74170	Ct abdomen w/o & w/dye
0333	76362	Ct guide for tissue ablation
Magnetic Resonance Imaging, Miscellaneous		
0335	70336	Magnetic image, jaw joint
0335	76393	Mr guidance for needle place
0335	76394	Mri for tissue ablation

0697	93304	Echo transthoracic
0697	93308	Echo exam of heart
0697	93321	Doppler echo exam, heart
0697	93325	Doppler color flow add-on

APPENDIX C: PFS HCPCS CODE FREQUENCY CALCULATION

Using the 2003 Physician/Supplier Procedure Summary Master File, we calculated the frequency of HCPCS codes in a PFS environment. These files, called BMAD files, are publicly available from CMS and published annually. The BMAD file is a 100% summary of all Part B Carrier and DMERC Claims processed through the Common Working File and stored in the National Claims History Repository. The file is arrayed by carrier, pricing locality, Healthcare Common Procedure Coding (HCPC), modifier 1, modifier 2, specialty, type of service, and place of service. The summarized fields are total submitted services and charges, total allowed services and charges, total denied services and charges, and total payment amounts.[7]

We began by using seven BMAD files (1, 7, 17, 18, 19, 21, and 23) which included the necessary HCPCS code ranges for imaging services. Because our study pertains only to the technical component, and this calculation was completed to maintain only procedure frequency, we deleted all claims only with a professional component, (i.e., those with modifier '26).

After deletion of the claims with only a professional component, claims were kept if the procedures were completed in an office, home, mobile unit, urgent care facility, independent clinic, end stage renal disease treatment facility or independent laboratory as designated by the numbers '11 , '12 , '15 , '20 , '49 , '65 , or '81 .

The denied procedure counts were deducted from the allowed procedure count for each HCPCS to obtain an allowed procedure count. If the 'reduced services' modifier, '52 , were present as either a primary or secondary modifier, the allowed procedure count was halved.

The HCPCS codes were then combined into one unique list of codes with the total allowed procedure counts.

DC1 865072v.1

[7] Physician/Supplier Procedure Summary Master File. CMS. www.cms.hhs.gov/nonidentifiabledatafile as viewed on April 27, 2006.

ADDENDUM B

Raw Data from the 93880 Survey Respondents

Addendum B

HCFA Labor Codes

Addendum B

CODE	DESC	RATE/m	RATE/hr
2143	RN/Ultrasound Tech	0.405	$ 24.30
4036	Ultrasound Tech	0.389	$ 23.34
6040	Vascular Tech	0.351	$ 21.06

Addendum B

Service Components

Addendum B

SURVEY ID:	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8
Service Component	**Min**	**Staff**	**Min**	**Staff**	**Min**	**Staff**	**Min**	**Staff**	**Min**	**Staff**	**Min**	**Staff**	**Min**	**Staff**	**Min**	**Staff**
Pre-Service Period Starts when appointment for study is made																
Review/read prior vascular lab studies, x-ray, lab, and pathology reports	10	VT	15	VT	3	OTH	2	RN,CVT	3	VT	10	JT/SON	5	VT	5	UT
Other Clinical Activity (please specify)																
Review Chart					2	OTH										
Clinical history											15	RN				
Check for appropriateness of test & verify MD order																
Prepare/fill out preliminary report form																
Scheduling, review orders, consult w/MD																
preauthorization/organization materials																
(BLANK)																
End: Patient arrival at office for study.																
Service Period Starts when patient arrives for study																
Greet patient/provide gowning	5	VT	2	VT	2	VT	3	RN,CVT	4	VT	7.5	T/SONO	3	VT	3	UT
Obtain informed consent			1	VT	2	VT	2	RN,CVT	2	VT			10	VT	5	UT
Obtain vital signs	5	VT	5	VT	2	VT	5	RN,CVT	2	VT	5	T/SONO/VT			5	UT
Prep and position patient	5	VT	2	VT	2	VT	3	RN,CVT	2	VT	4	T/SONO	4	VT	5	UT
Prepare room, equipment, supplies (select transducer, optimize gain, display, set sample volume, etc	5	VT	4	VT	3	VT	3	RN,CVT	4	VT	5	T/SONO	4	VT	5	UT
Perform exam,	60	VT	44	VT	62	VT	60	RN,CVT	44.5	VT	38	T/SONO	24	VT	42	UT
Collate preliminary data, arrange images, edit video tape	15	VT	5	VT	8	VT	10	RN,CVT	13	VT	5	T/SONO	6	VT	5	UT
Patient education/instruction/ counseling	5	VT	1	VT	6	VT	1	RN,CVT	2	VT	0.5	T/SONO	5	VT	5	UT
Coordinate home or outpatient care			1	VT	2	VT			0	VT					5	UT
Clean room/equipment	5	VT	3	VT	4	VT	3	RN,CVT	4	VT	4	T/SONO	1	VT	5	UT
Other Clinical Activity (please specify)																
Prepare Report					4	VT										
History, quest pt re:signs & symptoms, meds, family history									6	VT						
???SEE SURVEY??											7.5	T/SONO/VT				
log patient in book																
double check work - second observer checks key findings																
End: Patient leaves office																
Post-Service Period Starts when patient leaves office																
Phone calls between visits with ordering physician, patient, family	10	VT	5	VT	4	VT			1	VT						
Other Activity (please specify)																
Quality assurance activities									6	VT						
Prepare and fax prelim report to referring MD													6	VT	5	UT
Collection/correlation of results w/surgical and angiography/MRI/CT findings. Entry of data in computer database																
contact referring MD with results																
Quality assurance activities																
Preliminary reporting																
End: When appointment for next study is made (if necessary)																

9 Min	9 Staff	10 Min	10 Staff	11 Min	11 Staff	12 Min	12 Staff	13 Min	13 Staff	14 Min	14 Staff	15 Min	15 Staff	16 Min	16 Staff	17 Min	17 Staff	18 Min	18 Staff	19 Min
10	RVT	5	VT	3	VT	1	VT	5	SO	5	VT	5	VT	5	RN	5	VT	5	RVT	5
								3	SO											
		3	VT																	
						1	VT													
												5	VT							
														3	UST					
5	RVT	2	VT	3	VT	1	VT	3	SO	5	VT	3	VT	2	OTH	1	VT	5	RVT	5
2	RVT	1	VT	1	VT		VT							3	UST					
5	RVT	2	VT	2	VT	1	VT			2	OTH	5	VT	1	RN	3	VT	3	RVT	5
2	RVT	2	VT	1	VT	1	VT	3	SO	5	VT	1	VT	1	UST	1	VT	3	RVT	5
2	RVT	5	VT	2	VT	2	VT	3	SO	5	VT	3	VT	2	UST	2	VT	5	RVT	5
20	RVT	40	VT	36	VT	27	VT	70	SO	20	VT	60	VT	46	UST	26	VT	48	RVT	40
10	RVT	7	VT	12	VT	7	VT	5	SO	5	VT	10	VT	5	UST	4	VT	5	RVT	3
10	RVT,RN	3	VT	2	VT	2	VT			2	OTH	5	VT	5	RN	8	VT	3	RVT	
0	RVT	10	RN											3	RN	1	receptionist			
4	RVT	4	VT	2	VT	11	VT	5	SO	2	VT	3	VT	5	OTH	3	VT	5	RVT	3
								2	SO											
10	RVT	15	RN			5	VT			5	OTH	5	VT	5	RN	2	VT	5	RVT	
												10	VT							

19 Staff	20 Min	20 Staff	21 Min	21 Staff	22 Min	22 Staff	23 Min	23 Staff	24 Min	24 Staff	25 Min	25 Staff	26 Min	26 Staff	27 Min	27 Staff	28 Min
UST	2	T,CVN,LPN	2	T,CVN,LPN	2	VT	5	RN	2	VT	5	SO	10	RN/VT	9	VT	5
													10	RN			
UST	3	T,CVN,LPN	3	T,CVN,LPN	1	VT	1	RN	2	VT	5	SO	5	RN/VT	5	VT	5
	2	T,CVN,LPN	2	T,CVN,LPN,RVT...			1	RN	2	VT			3	RN/VT	5	VT	
UST	5	T,CVN,LPN	5	T,CVN,LPN	4	VT	2	RN	3	VT	2	SO	3	RN	7	VT	
UST	3	T,CVN,LPN	3	T,CVN,LPN	1	VT	1	RN	2	VT	1.5	SO	2	RN/VT	2	VT	3
UST	3	T,CVN,LPN	3	T,CVN,LPN	2	VT	2	RN	2	VT	1.5	SO	5	RN/VT	9	VT	4
UST	60	T,CVN,LPN	60	T,CVN,LPN	34.5	VT	44	RN	30	VT	39	SO	28	RN/VT	40	VT	27
UST	10	T,CVN,LPN	10	T,CVN,LPN	10	VT	2	RN	5	VT	7	SO	5	RN/VT	25	VT	5
	1	T,CVN,LPN	1	T,CVN,LPN	2	VT	2	RN	5	VT			10	RN/VT	3	VT	
									2	RN			30	RN			
UST	3	T,CVN,LPN	3	T,CVN,LPN	5	VT	2	RN	2	VT	1.5	SO	5	RN/VT	6	VT	3
					2	VT	1	RN	3	VT			20	RN			
							8	RN									
													13	RN/VT			

28 Staff	29 Min	29 Staff	30 Min	30 Staff	31 Min	31 Staff	32 Min	32 Staff	33 Min	33 Staff	34 Min	34 Staff	35 Min	35 Staff	36 Min	36 Staff	37 Min
UST	1	VT	2		10	VT	2	VT	4	VT	2	VT	3	SO	5	VT	
UST	5	VT	3		5	VT	2	VT	3	VT	5	SO/VT	3	SO	2	VT	
	3	VT	2		5	VT			2	VT	5	VT	2	SO			
	1	VT	3				2	VT	2	VT	1		4	SO	2	VT	
UST	0.5	VT	2		5	VT	1	VT	2	VT	1		1	SO	1	VT	
UST	3	VT	2		5	VT	1	VT	2	VT	5		1	SO	2	VT	
UST	29	VT	50		60	VT	49	VT	45.5	VT	22	VT	20	SO	44	VT	60
UST			2		15	VT	5	VT	8	VT	60	VT	10	SO	2	VT	
	2	VT	3				3	VT	2	VT	10		4	SO	1	VT	
			2														
UST	2	VT	1		5	VT	2	VT	3	VT	5		2	SO	1	VT	
			5														
			3		10	VT	1	VT									
	7	VT															
			5						6	VT							

37 Staff	38 Min	38 Staff	39 Min	39 Staff	40 Min	40 Staff	41 Min	41 Staff	42 Min	42 Staff	43 Min	43 Staff	44 Min	44 Staff	45 Min	45 Staff	46 Min
	8	VT	5		10	VT	2		2	VT	3	VT	2	VT	5	VT	5
							3								5	RN	
																	5
	2	VT	6		5	VT	1		1	VT	2	VT	2	VT	5	VT	5
	4	VT	2		2	VT	0		2	VT	0	VT	0	VT	5	VT	0
	2	VT	6		2	VT	0		2	VT	5	VT	0	VT	5	VT	0
	10	VT	3		1	VT	2		2	VT	3	VT	2	VT	2	VT	3
	5	VT	4		1	VT	3		3	VT	3	VT	2	VT	6	VT	5
VT	80	VT	40.5		42	VT	32		50	VT	33	VT	41	VT	36	VT	35
	15	VT	15		10	VT	3		12	VT	10	VT	3	VT	2	VT	7
	3	VT	4		5	VT	1		7	VT	5	VT	3	VT	2	VT	2
	5	VT	3		5	VT	0				0	VT	0	VT	0	VT	0
	3	VT	5		2	VT	2		1	oth	5	VT	1	VT	2	VT	2
																	3
	10	VT	5				3		7	oth	10	VT/LPN					5
	10						10						6	VT	10	VT	
											10	VT	5	VT			
					15												

Staff	Min	Staff	Min	Staff	Min	Staff	Min	Staff	Min	Staff

14	gel	ml	25
14	gloves	pair	2
14	pillow case		1
14	printer paper	sheets	4
14	towels		2
14	video tape	each	1
15	gel	liter	30ml
16	gel		2oz
16	gloves	pair	1
16	gowns	each	1
16	printer paper	roll	10 sheets
16	VHS tape	each	1
17	gel		1oz
17	photo		1
17	towels		2
18	electrodes		3
18	gel		.10 bottle
18	tapes		1
19	exam table paper		
19	gel	oa	2
19	gown		
19	paper for report		
19	pillwcase		
19	record log book		
19	towels		
19	washcloths		
21	Aquasonic Gel	10 ml	10
21	Drape sheet	Item	1
21	Enviroside cleanser	Oz.	10
21	Gloves, nonsterile	Pair	1
21	Kleenex	box	Lots ;-)
21	Patient Education brochure	Item	1
21	Patient gown, disposable	Item	1
21	Pillow case, disposable	Item	1
21	VHS Tape	Item	1
22	gel	oz	5
22	paper towels	roll	0.125
22	table sheet	50/case	1
22	thermal printer paper	roll	0.1
22	video tape	each	0.1
23	exam table paper	roll	8 ft
23	gel	bottle	"some squirts"
23	kleenex	box	2 tissues
23	optical disc	disc	1

23	pa-er towel	roll	6
23	pillow towel	each	1
23	pillowcase	each	1
23	sony film	page	4
24	exam table paper	ft	6
24	kleenex	each	4
24	pillow case	each	1
24	towels	each	2
25	bed seet	each	1
25	gel - ultrasound	liter	15ml
25	gloves	pair	1
25	printer paper	each	0.2
25	video tape	each	0.1
26	disposable wipes	each	6
26	exam table paper	ft	7
26	gel	liter	2
26	printer paper	meter	1.25
27	Paper for exam table	Roll	8 ft per study
27	Paper towels	Case	4 sheets per study
27	Photo paper	Roll	2 feet
27	Transducer cleaner	Ml	4-5 sprays
27	Ultrasound Gel	Ounce	2 oz
27	Video cassette	Ea.	.20 of tape
29	K Dry Towels	90 per box	6
29	Water Soluble Ultrasound Gel	5 liters	20
29	Paper Drape	100 per box	1
30	Blue pads --- chux	1	2
30	Linen sheets, pillowcases	1 set	1
30	Paper washcloths to remove gel a	1	4
30	Ultrasound gel	One bottle	0.05
30	Isopropyl alcohol	One bottle pt	0.1
30	Acuson film	Cartridge	8 film pieces
30	Sony magneto-opt disk	disk reusable	1
30	Ecg paper	1 roll	0.03
30	Adhesive tape for mounting picture	1 roll	0.01
30	Binders for reports manila binders	1	1
30	Pendaflex suspension folders	1	1
30	Copy paper for reports	1 ream	4 sheets
30	Pens, pencils, paper clips, marking pencils		
30	Tape measure		
30	scissors		
31	Ultrasound Gel	5 Liter	5 ml
31	Paper for hard copy	ream	2 pages
31	Photographic Paper (B&W)	roll	10 images X3" each

31	Photographic Paper (color)	ream	3-4 pages
31	Sheets		1
31	Patient Gowns		1
32	Bed Sheet (Linen Service)	Prn	1
32	Tissue Paper	)x 100 sheets	16
32	Ultrasound Gel	5 liter	120 ml
32	SVHS Tape (120 minutes)	1	8 minutes
32	Sony UPP-110 HA Paper (110 mn	5 rolls	170 mm
33	Patient Education Pamphlet	1 pamphlet	1
33	Video Tape	Tape	0.5
33	Color Print Paper	100 Pack	3 Prints
33	Ultrasound Coupling Gel	5 liters	30 ml
33	Disposable gloves	Box	2 gloves
33	Patient exam table sheet "paper"	Box	1 gown/drape
33	Paper towels	Case	< 1 role
33	Disinfectant spray	Bottle	% of total (2%)
34	gel		50cc
34	ekg pads		3
34	sheets		1
34	gown		1
34	vido tape		1
35	gel	gallon	4oz
35	paper towel	carton	4
35	mo disk	box	2.9mb
35	sheet	roll	6ft
35	sanitizer	gallon	2 oz
35	printer paper color	box	1
35	printer paper bw	bos	3.5
35	ink cartridge	pak	1oz
36	gel		1oz
36	video tape		
37	gel		
37	color paper		4
37	bw paper		24
37	towels		4
38	video tape		
38	therma paper		
38	color paper		
38	gel		
38	table paper		
38	gowns drapes		
38	transducer cleaning soluntion		
39	gel	5 liter	4oz
39	sony paper	roll	1/6

39	vcr tapes	1	1/12
39	paper towels		20
39	table paper	case	
39	drapes	case	2
39	stand offs	box of 5	1
39	magic markers	1	
39	gloves	box	2
39	tourniquets	14"	
39	double sided tape	roll	
39	disinfect transducer spray	8oz	1/2 oz
39	work sheets		
39	ref books		
39	tiltable stretchers		
39	gel warmers		
39	tegaderm sheeets	box	1-2
39	sterile gel packages	3oz	1
39	treadmill		
40	gel	5 liter	10ml
40	printer paper	110mmx20m	0.5 m per pt
41	gel	case	0.08 liter
41	color printing paper	box	2-3
41	mounting forms	case	2-3
42	sony upc paper	200/box	10-15 single
42	gel	8oz	2oz
42	thermal paper		5ft
43	Gel	8 oz. Botles	.5 – 3 ounces
43	Gloves	Box of 100	2
43	Videotapes	Box of 12	1/10 of tape
43	Printer paper/ribbon	)ages a box)`	2 sheets of printer paper
43	Cleanser	12 oz. Bottles	5 squirts
44	Sony Color Print Paper	‹ - 200 pages	4-6 pages
44	Ultrasound Gel	iter container	10 ml
44	Table exam paper	roll	7 ft
44	Linen - pillowcase		1
44	Linen - sheet		Used for a day of pts.
44	Linen - face cloth		2
45	gel	250	5
46	gel	1 gal	4-8 oz
46	sony color prints film	case	2-4 prints
46	vcr tapes	8 per case	7-10 min
46	laundry - wahscloths, pillow case	3 doz/week	3-5 items
46	exam table paper	case	12 feet
46	gloves	case	2
46	cleaning fluid		3oz

Med Equip

Addendum B

SVY ID	Medical Equipment	No. Units	Min/Proc	Hrs/Wk
1	Duplex ultrasound system	5	30	38
2	Duplex Ultrasound Scanner	8	44	60
2	Picture Archiving / Data System	1	50	80
2	CW Doppler / Plethysmography	5	5	60
3	Duplex Ultrasound Machine	3	70	75
4	Ultrasound room with Doppler	-	-	-
4	SVHS Video Recorder	-	-	-
4	Exam table	-	-	-
4	Viewbox, 2 panel	-	-	-
4	Review station, AG7300 SVHS,	-	-	-
5	Color Duplex Scanner	1	41	40
5	Examination Table	1	45	40
5	SVHS Video Tape recorder	2	30	40
5	Color video printer	1	10	40
6	ATL 3500 Duplex Imaging Syste	1	18	40
7	Duplex Ultrasound Scanner	4	24	28
8	Phillips Ultrasound Machine	1	42	50
9	Duplex Ultrasound Scanner	2	20	40
9	Br?? PVL & spectrol analysis	1	10	15
10	Duplex Ultrasound Scanner	1	40	15
10	non-imaging doppler machine	1	30	2
21	Ultrasound room with Doppler	-	-	-
21	SVHS Video Recorder	-	-	-
21	Exam table	-	-	-
21	Viewbox, 2 panel	-	-	-
21	Review station, AG7300 SVHS,	-	-	-
27	GE Vivid Three	1	40-50	30-40
27	HP 2000	1	40-50	20
27	View box	4		
11	duplex	1	38	30
12	ATL	2	27	45
13	ATL	1	70	30
14	Sono 5500 US machine	4	20	120
14	Sono 4500 US machine	1	20	30
14	linear probe	5	17	45
14	exam table	5	20	150
14	VCR	5	13	100
14	printer	5	4	1
15	ATL 5000	3	60	50
16	ATL	1	15	30
17	GE logic	1	15	12
17	ATA Ultramark 9	1	15	12
18	Toshiba 6000	2	60	40

POSSIBLITITES

E52009	Software (Paceart)	6,000.00	0.02537
E52010	Sony Color Video Printer	10,500.00	0.04440
E52012	SVHS video recorder	599.00	0.00253
E52013	Review Station: AG7300 SVHS,17in.	899.99	0.00381
E52014	Rigiscan	12,500.00	0.04211
E52015	a-mode ultrasonic biometry unit	6,950.00	0.02939
E52016	b scan ultrasonography	24,975.00	0.10562
E52017	potential acuity devices	3,195.00	0.01351
E52018	Ultrasound Room	272,000.00	1.12585
E52019	Ultrasonic nebulizer	1,000.00	0.00293
E52020	Acusonic Sequoia C0256	250,000.00	
PEAC	ultrasound table	4,495.00	0.01317
PEAC	Ultrasound Unit	30,000.00	0.12417
PEAC	video system	10,000.00	0.05981

18	probe	1	45	8
22	ATL 3500	3	35	105
23	Aculson aspen imager	4	40	35
23	oxford doppler	4	5	35
24	doppler	4	30	40
24	transducer	4	30	40
24	computers	10	30	40
24	software	4	5	40
25	HP 2000 echocaradiograph	1	39	35
25	transducer 6.5 mHz	1	39	5
25	Acuson sequoia echocardiograp	2	39	36
25	transducer 6 mHz	1	39	15
25	transducer 8 mHz	1	39	5
26	Acuson US	1	28	24
26	database	1	15	30
26	computer	1	30	40
29	ATL 5000 Color Duplex Ultrasou	5	30	45
29	Exam Tables/Stretchers	5	30	45-50
29	Computer Terminal	5	10	50-55
29	ALI Reviewing Station	1	5	20-25
29	Philips PACS Image Manageme	1	10	60
30	Acuson Aspen ultrasound machi	3	50	40 each
30	Sphygomanometer	3	5	40
30	Stethoscopes	5	5	40
30	Stretchers for patients during pr	3	50	40
30	Stand/step to assist in mounting	3	1	40
30	Chairs for family/friends for exa	6	50	40
30	Chairs for our separate waiting r	12	15	40
31	Duplex ultrasound machine	5	60	35
32	GE Logiq 700	1	50	40
32	Sony UP-890 MD B/W Printer	1	20	10
32	Parks model 811-B Dopler	2	2	20
32	Diasonics VST	1	50	20
33	Color Flow Duplex Imager	5	40	40
33	Video Recorder	5	30	40
33	Color Printer	5	12	40
34	GE v-5	3	60	40
34	aspen duplex	2	20	20
34	gateway 2000 computer	2	15	12
35	HP1000		60	40
35	HP4500		60	40
35	HP 5500		60	40
37	parks holab	1	30	50
37	ATL ultramark	1	90	50

37	treadmill	1		50
37	hand held doppler	1		50
38	duplex scanner	4	30	12
38	exam table	4	30	16
38	scan head	3	30	8
39	ATL 3000	2	45	34
40	duplex	5	42	15
41	ATL 5000	2	45	60/unit
42	Toshiba 6000	1	40	40
43	Acuson XP10	2	40	32
43	Sony Printer	2	40	32
43	VCR Regular	1	40	32
43	VCR Super	1	40	32
43	Stretcher	2	50	32
43	Gel warmer	3	Constantly	Constantly
44	Siemens Quantum 2000	1		32
44	Siemens Elegra	1		20
44	ATL 3000	3		40
44	ATL 5000	2		40
44	Adjustable patient stretcher	6	45-50	40
44	Adjustable exam chair	6		40
45	prob	4	36	5
45	HP 5500 US	8	36	5
46	ATL apogee	1	35	24
46	hausted exam table	1	35	24
47	SD 800	3	42	
47	ATL	1	42	

Exam Details

Addendum B

SURVEY ID:	1	1	2	2	3	3	4	4	5
Exam Details	**Rt**	**Lt**	**Rt**	**Lt**	**Rt**	**Lt**	**Rt**	**Lt**	**Rt**
TOTAL	**30**	**30**	**22**	**22**	**31**	**31**	**30**	**30**	**22.25**
CCA 1st Site B-Mode Longitudinal View(s)	1	1	0.5	0.5	1	1	1	1	0.5
CCA 1st Site B-Mode Transverse View(s)	1	1			1	1	1	1	0.5
CCA 1st Site Doppler Spectral Data	2	2	2	2	1	1	1	1	0.5
CCA 1st Site Color Flow Data	1	1			1	1	1	1	0.25
CCA 2nd Site B-Mode Longitudinal View(s)	1	1	0.5	0.5	1	1	1	1	0.5
CCA 2nd Site B-Mode Transverse View(s)	1	1	0.5	0.5	1	1	1	1	0.5
CCA 2nd Site Doppler Spectral Data	2	2	2	2	1	1	1	1	0.5
CCA 2nd Site Color Flow Data	1	1			1	1	1	1	0.25
ICA 1st Site B-Mode Longitudinal View(s)	1	1	0.5	0.5	3	3	1	1	2
ICA 1st Site B-Mode Transverse View(s)	1	1	0.5	0.5	2	2	1	1	2
ICA 1st Site Doppler Spectral Data	5	5	2	2	3	3	1	1	2
ICA 1st Site Color Flow Data	1	1	1	1	2	2	1	1	2
ICA 2nd Site B-mode Longitudinal View(s)	1	1	0.5	0.5	3	3	1	1	2
ICA 2nd Site Doppler Spectral Data	4	4	2	2	2	2	1	1	2
ICA 2nd Site Color Flow Data	1	1	1	1	2	2	1	1	1.5
ECA B-mode Longitudinal View(s)	1	1	1	1	1	1	1	1	0.25
ECA Doppler Spectral Data	1	1	2	2	1	1	1	1	0.25
ECA Color Flow Data	1	1	1	1	1	1	1	1	0.25
Vertebral B-mode Longitudinal View(s)	1	1	0.5	0.5	1	1	1	1	0.5
Vertebral Doppler Spectral Data	1	1	2	2	1	1	2	2	0.75
Vertebral Color Flow Data	1	1			1	1	1	1	0.25
Other: Please list vessel or site:									
ICA 3rd Site B-mode			0.5	0.5					
ICA 3rd Site Doppler Spectral Data			2	2					
Subclavian artery							2	2	1
ECA 2nd site - distally							2	2	
ICA & CCA 3rd sites (B-mode/Doppler/Color)							4	4	
Additional views of diseased segment									2
Bulb - color flow % doppler trans & long									
Additional views of diseased vessel									
Stenotic / shift areas									

5 Lt	6 Rt	6 Lt	7 Rt	7 Lt	8 Rt	8 Lt	10 Rt	10 Lt	11 Rt	11 Lt	12 Rt	12 Lt
22.25	**19**	**19**	**13.8**	**13.8**	**21**	**21**	**20**	**20**	**18**	**18**	**13.5**	**13.5**
0.5	2	2	0.5	0.5	1	1	1	1	1	1	0.5	0.5
0.5	2	2	0.2	0.2	1	1	0.5	0.5	0.5	0.5	0.5	0.5
0.5	2	2	0.25	0.25	1	1	0.5	0.5	1	1	0.5	0.5
0.25	1	1	0.2	0.2	1	1	1	1	1	1	0.5	0.5
0.5	1	1	0.5	0.5	1	1	1	1	1	1	0.5	0.5
0.5	1	1	0.2	0.2	1	1	1	1	0.5	0.5	0.5	0.5
0.5	1	1	0.25	0.25	1	1	1	1	1	1	0.5	0.5
0.25	1	1	2	2	1	1	1	1	1	1	0.5	0.5
2	1	1	1	1	1	1	1	1	1	1	0.5	0.5
2	0.5	0.5	0.3	0.3	1	1	1	1	0.5	0.5	0.5	0.5
2	0.5	0.5	1	1	1	1	1	1	1	1	1	1
2	0.5	0.5	1	1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1	1	0.5	0.5	1	1
2	0.5	0.5	1	1	1	1	1	1	1	1	1	1
1.5	0.5	0.5	1	1	1	1	1	1	1	1	1	1
0.25	0.5	0.5	0.2	0.2	1	1	1	1	0.5	0.5	0.5	0.5
0.25	0.5	0.5	0.4	0.4	1	1	1	1	1	1	0.5	0.5
0.25	0.5	0.5	0.2	0.2	1	1	1	1	1	1	0.5	0.5
0.5	1	1	1	1	1	1	1	1	0.5	0.5	0.5	0.5
0.75	0.5	0.5	0.4	0.4	1	1	1	1	1	1	0.5	0.5
0.25	0.5	0.5	0.2	0.2	1	1	1	1	1	1	0.5	0.5
1			1	1							0.5	0.5
2												

13 Rt	13 Lt	14 Rt	14 Lt	15 Rt	15 Lt	16 Rt	16 Lt	17 Rt	17 Lt	18 Rt	18 Lt	19 Rt
35	35	22	22	30	30	22	22	13	13	24	24	22
5	5	1	1	1	1	1	1	0.25	0.25	1	1	1
3	3	1	1	1	1	1	1	0.25	0.25	1	1	1
3	3	1	1	1	1	1	1	0.5	0.5	1	1	1
0	0	1	1	1	1	1	1	0.5	0.5	1	1	1
0	0	1	1	1	1	1	1	0.25	0.25	1	1	1
0	0	1	1	1	1	1	1	0.25	0.25	1	1	1
2	2	1	1	1	1	1	1	0.5	0.5	1	1	1
0	0	1	1	1	1	1	1	0.5	0.5	1	1	1
0	0	1	1	1	1	1	1	1	1	2	2	1
0	0	1	1	1	1	1	1	0.5	0.5	1	1	1
5	5	1	1	2	2	1	1	1	1	1	1	1
2	2	1	1	2	2	1	1	0.5	0.5	1	1	1
0	0	1	1	1	1	1	1	1	1	2	2	1
3	3	1	1	2	2	1	1	1	1	1	1	1
2	2	1	1	2	2	1	1	0.5	0.5	1	1	1
0	0	1	1	1	1	1	1	0.5	0.5	1	1	1
3	3	1	1	1	1	1	1	1	1	1	1	1
0	0	1	1	1	1	1	1	0.5	0.5	1	1	1
2	2	1	1	1	1	1	1	1	1	1	1	1
2	2	1	1	1	1	2	2	1	1	1	1	1
0	0	1	1	1	1	1	1	0.5	0.5	1	1	1
3	3	1	1							1	1	1
				5	5							

19 Lt	20 Rt	20 Lt	21 Rt	21 Lt	22 Rt	22 Lt	23 Rt	23 Lt	24 Rt	24 Lt	25 Rt	25 Lt
22	**30**	**30**	**30**	**30**	**17.25**	**17.25**	**22**	**22**	**14.75**	**14.75**	**19.5**	**19.5**
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	1	1	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	1	1	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	1	1	1	1
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	1	1
1	1	1	1	1	1	1	1	1	2	2	2.5	2.5
1	1	1	1	1	0.75	0.75	1	1	1	1	2	2
1	1	1	1	1	0.75	0.75	1	1	1	1	1	1
1	1	1	1	1	1	1	2	2	1	1	2.5	2.5
1	1	1	1	1	0.75	0.75	1	1	1	1	2	2
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	1	1	1	1	0.5	0.5	1	1
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.25	0.25	0.5	0.5
1	2	2	2	2	1	1	1	1	0.5	0.5	0.5	0.5
1	1	1	1	1	0.75	0.75	1	1	0.5	0.5	0.5	0.5
1	2	2	2	2					0.5	0.5		
	2	2	2	2								
	4	4	4	4								

26 Rt	26 Lt	27 Rt	27 Lt	28 Rt	28 Lt	29 Rt	29 Lt	30 Rt	30 Lt	31 Rt	31 Lt	32 Rt
14	**14**	**20.5**	**20.5**	**13.5**	**13.5**	**14.5**	**14.5**	**26**	**26**	**30**	**30**	**23.5**
0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	0.5
0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5			1	1	0.5
1	1	1	1	1	1	0.75	0.75	1	1	2	2	1
0.25	0.25	1	1	0.5	0.5	0.5	0.5	1	1	1	1	0.5
0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	0.5
0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	0.5
1	1	1	1	1	1	0.75	0.75	1	1	2	2	0.5
0.25	0.25	1	1	0.5	0.5	0.5	0.5	1	1	1	1	0.5
1	1	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	2.5
1	1	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	2.5
1	1	2	2	1	1	1.25	1.25	2	2	5	5	1.5
0.5	0.5	1	1	0.5	0.5	0.5	0.5	2	2	1	1	1
1	1	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	1
1	1	2	2	1	1	1.25	1.25	2	2	4	4	1
0.5	0.5	1	1	0.5	0.5	0.5	0.5	2	2	1	1	0.5
0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	1
0.5	0.5	1	1	1	1	0.5	0.5	1	1	1	1	1
0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5	1	1	1	1	0.5
1	1	1	1	0.5	0.5	0.5	0.5	1	1	1	1	1
1	1	1	1	1	1	1.25	1.25	1	1	1	1	1
0.5	0.5	1	1	0.5	0.5	0.5	0.5	1	1	1	1	0.5
1	1					1.25	1.25	2	2			
												4
		2	2									

32 Lt	33 Rt	33 Lt	34 Rt	34 Lt	35 Rt	35 Lt	36 Rt	36 Lt	38 Rt	38 Lt	39 Rt	39 Lt
23.5	**22.75**	**22.75**	**10.75**	**10.75**	**10.00**	**10.00**	**22**	**22**	**40**	**40**	**18.75**	**18.75**
0.5	0.5	0.5	0.25	0.25	0.48	0.48	1	1	2	2	1.5	1.5
0.5	0.5	0.5	0.25	0.25	0.48	0.48	1	1	1.5	1.5	1	1
1	0.5	0.5	0.5	0.5	0.48	0.48	1	1	1.5	1.5	1.5	1.5
0.5	0.25	0.25	0.5	0.5	0.48	0.48	1	1	2	2	0.25	0.25
0.5	0.5	0.5	0.25	0.25	0.48	0.48	1	1	1	1	1	1
0.5	0.5	0.5	0.25	0.25	0.48	0.48	1	1	0.5	0.5	1	1
0.5	0.5	0.5	0.5	0.5	0.48	0.48	1	1	0.5	0.5	1	1
0.5	0.25	0.25	0.5	0.5	0.48	0.48	1	1	1	1	0.25	0.25
2.5	2	2	0.5	0.5	0.48	0.48	1	1	4	4	1	1
2.5	2	2	0.25	0.25	0.48	0.48	1	1	2.5	2.5	1	1
1.5	2	2	1	1	0.48	0.48	1	1	1	1	1	1
1	1.75	1.75	1	1	0.48	0.48	1	1	3	3	0.25	0.25
1	2	2	0.5	0.5	0.48	0.48	1	1	3	3	1	1
1	2	2	1	1	0.48	0.48	1	1	1	1	1	1
0.5	1.25	1.25	1	1	0.48	0.48	1	1	1	1	0.5	0.5
1	0.25	0.25	0.5	0.5	0.48	0.48	1	1	1	1	0.5	0.5
1	0.25	0.25	0.25	0.25	0.48	0.48	1	1	1	1	1	1
0.5	0.25	0.25	0.25	0.25	0.48	0.48	1	1	5	5	0.5	0.5
1	0.5	0.5	0.5	0.5	0.48	0.48	1	1	4	4	0.25	0.25
1	0.75	0.75	0.5	0.5	0.48	0.48	1	1	0.5	0.5	1	1
0.5	0.25	0.25	0.5	0.5	0.48	0.48	1	1	1	1	0.25	0.25
	2	2					1	1	2	2	2	2
4												
	2	2										

40 Rt	40 Lt	41 Rt	41 Lt	42 Rt	42 Lt	43 Rt	43 Lt	44 Rt	44 Lt	45 Rt	45 Lt	46 Rt
21	21	16	16	23.5	35.5	18.7	14.3	20.5	20.5	15.97	15.97	17.5
2	2	0.5	0.5	1	1	0.2	0.2	0.5	0.5	0.25	0.25	0.5
1	1	0.5	0.5	1	1	0.1	0.1	0.5	0.5	0.25	0.25	0.5
1	1	1	1	1	1	1.0	0.4	0.5	0.5	0.25	0.25	0.5
0	0	0.5	0.5	1	1	0.2	0.4	0.5	0.5	0.25	0.25	0.5
1	1	0.5	0.5	1	1	0.3	0.3	0.5	0.5	0.25	0.25	0.5
0.5	0.5	0.5	0.5	1	1	0.1	0.1	0.5	0.5	0.25	0.25	0.5
2	2	1	1	1	1	1.3	0.8	0.5	0.5	0.25	0.25	0.5
0	0	0.5	0.5	1	1	0.2	0.8	0.5	0.5	0.25	0.25	0.5
1	1	1	1	2	2	0.3	0.3	3	3	0.71	0.71	1
1	1	0.5	0.5	1	2	0.2	0.2	0.5	0.5	0.71	0.71	1
2	2	1	1	1	1.5	2.0	1.5	5	5	0.71	0.71	1
0	0	0.5	0.5	1	1.5	0.8	1.5	3	3	0.71	0.71	1
1.5	1.5	1	1	1	3.5	0.5	0.6	0.5	0.5	0.71	0.71	1
2	2	1	1	1	2.5	6.0	1.0	0.5	0.5	0.71	0.71	1
0	0	0.5	0.5	1	2.5	0.8	0.8	0.5	0.5	0.71	0.71	1
1	1	1	1	1	1	0.3	0.3	0.5	0.5	1.67	1.67	0.5
1	1	1	1	1	1	2.3	0.8	0.5	0.5	1.67	1.67	0.5
0	0	0.5	0.5	1	1	0.2	0.2	0.5	0.5	1.67	1.67	0.5
2	2	0.5	0.5	1	1	0.3	1.0	0.5	0.5	1.33	1.33	1
1	1	1	1	1	1	0.4	0.8	1	1	1.33	1.33	1
0	0	0.5	0.5	1	1	1.0	1.5	0.5	0.5	1.3	1.3	1.0
1	1	1	1			0.5	1.0					1
												1
				1.5	6							

46 Lt	47 Rt	47 Lt	MEDIAN One side	MEDIAN Two sides	SUM B-Mode	SUM Colorflow	SUM Doppler	OTHER	TOTAL
17.5	21	21	21	42					
0.5	1	1	1.00	2.00	2.00				
0.5	1	1	0.75	1.50	1.50				
0.5	1	1	1.00	2.00			2.00		
0.5	0.5	0.5	0.63	1.25		1.25			
0.5	1	1	1.00	2.00	2.00				
0.5	1	1	0.50	1.00	1.00				
0.5	1	1	1.00	2.00			2.00		
0.5	1	1	1.00	2.00		2.00			
1	1	1	1.00	2.00	2.00				
1	1	1	1.00	2.00	2.00				
1	0.5	0.5	1.00	2.00			2.00		
1	1	1	1.00	2.00		2.00			
1	1	1	1.00	2.00	2.00				
1	1	1	1.00	2.00			2.00		
1	1	1	1.00	2.00		2.00			
0.5	1	1	1.00	2.00	2.00				
0.5	1	1	1.00	2.00			2.00		
0.5	0	0	0.50	1.00		1.00			
1	1	1	1.00	2.00	2.00				
1	1	1	1.00	2.00			2.00		
1.0	0.0	0.0	1.00	2.00		2.00			
1									
1	3	3							
				SUM	16.50	10.25	12.00	3.25	42.00
				% EXAM TIME	39%	24%	29%	8%	100%

Miscellaneous

Addendum B

Survey ID	1	2	3	4	5	6	7	8	9
Reference Code 1	93975	93970	93970	x	93978	93978	93307	x	93925
Reference Code 2	93926	93925	93975	x	93971	93971	93975	x	93970
Typical credential of individuals in your lab who perform CPT 93880	RVT	RVT	RVT	RDMS/RVT	MS,RDCS	RVT	RVT, CVT	RVT	RVT
Number of individuals in your lab who perform CPT 93880	6	11	3	40	2	3	5	2	2
Average hourly salary of individuals in your lab who perform CPT 93880	$ 22.00	$ 21.50	$ 33.00	$ 27.43	$ 26.34	$ 22.00	$ 26.42	$ 22.00	$ 24.04

10	11	12	13	14	15	16	17	18	19	20	21	22
93886	x	93970	x	93925	93925	93925	x	93307	x	93307	93307	93970
93882	x	93978	x	93970	93970	93978	x	93320	x	93320	93320	93925
RVT	RVT,RVS	VT,SDMS	RVT	RVT	RVT	RVT	RVT	RVT	RDCS	DMS/RVT	DMS/RVT	RVT
2	2	2	2	3	5	2	2	1	2	4	6	3
$ 16.15	$ 22.00	$ 25.00	$ 20.00	$ 31.00	$ 25.00	$ 40.00		$ 35.00	$ 24.00	$ 31.46	$ 29.69	$ 26.00

23	24	25	26	27	28	29	30	31	32	33	34	35
93970	93925	93925	93926	93970	x	93930	x	93925	93925	93320	93970	93970
93925	93978	93970	93970	93971	x	93970	x	93975	93970	93307	93925	93925
RN,RVT	RVT RDCS,RCS		RN,RVT	RVT ,RDMS,RT		RVT	RVT, RN	RVT	RVT	RVT RDMS,RVT		RVT
5	5	4	1	1	5	7	5.5	5	1	6	1	3
$ 30.00	$ 27.35	$ 24.00	$ 25.00	$ 20.00	$ 25.00	$ 25.50	$ 23.00	$ 22.00	$ 38.50	$ 23.00	$ 22.50	$ 26.00

36	37	38	39	40	41	42	43	44	45	46	47	48
93350	x	x	93970	93886	93970	93925	93970	93970	93970	xx	93307	
93320	x	x	93978	93925	93978	93970	93925	93926	93978	xx	xxx	
RVS	RVT	RVT	RVT	RVT	RVT	RVT	DMS, RVT	RVT	VT, RDCS	RVT	RVT	
1	1	7	8	1	5	2	3	7	7	1	4	
$ 31.50	$ 33.65	$ 21.00	$ 27.00	$ 25.00	$ 27.92	$ 27.00	$ 19.40	$ 26.60	$ 22.98	$ 25.00	ith benes)	

49 50 51

ADDENDUM C

SVS Cumulative Time Spreadsheet

Addendum C

	A	B	C	D	E	F	G	H	I
1				CPT	93880TC	93882TC	93886TC	93888TC	93875TC
2			Survey / Crosswalk		survey	crosswalk	survey	crosswalk	crosswalk
3	IN-OFFICE: Clinical Labor, Medical Supplies, and Procedure Equipment Practice Expense Data			Descriptor:	Duplex scan of extracranial arteries; complete bilateral study	Duplex scan of extracranial arteries; unilateral or limited study	Transcranial Doppler study of the intracranial arteries; complete study	Transcranial Doppler study of the intracranial arteries; limited study	Noninvasive physiologic studies of extracranial artery
4	**CLINICAL LABOR**	Code	Staff	Price					
5	2002 CMS CPEP TOTAL TIME	040	Vasc Tech	$ 0.540	95	65	105	75	35
6	ACR Proposed Times				62	43	62	43	43
7	Original Consortium Proposed Time				88	62	97	68	40
8	Proposed Consortium/ACR blend Time				84	61	95	67	40
9	PEAC PreFacilitation and Final PEAC Time				82	59	92	64	37
10									
11	**PROPOSED Consortium/ACR blend TOTAL TIME**	040	Vasc Tech	$ 0.540	84	61	95	67	40
12	**Proposed pre-service time**	040	Vasc Tech	$ 0.540	5	5	6	8	2
13	**Proposed SERVICE time**	040	Vasc Tech	$ 0.540	71	48	81	53	32
14	**Propose post-service time**	040	Vasc Tech	$ 0.540	8	8	8	8	6
15	**PRE-SERVICE**								
16	**Starts when appointment for study is made**				Min	Min	Min	Min	Min
17	Review/read prior vascular lab studies, x-ray, lab, and pathology reports	040	Vasc Tech	$ 0.540	4	4	5	5	1
18	**Other Pre-Service Activities (please specify):**								
19	Review orders, consult w/MD, log study, solve scheduling dilemmas	040	Vasc Tech	$ 0.540	1	1	1	1	1
20	***End: Patient arrival at office for study.***								
21	**SERVICE PERIOD**								
22	**Starts with admission to facility/office**				Min	Min	Min	Min	Min
23	Greet patient/provide gowning	040	Vasc Tech	$ 0.540	3	3	3	3	3
24	Obtain informed consent	040	Vasc Tech	$ 0.540	0	0	0	0	0
25	Obtain vital signs	040	Vasc Tech	$ 0.540	3	3	3	3	3
26	Prep and position patient	040	Vasc Tech	$ 0.540	3	3	3	3	3
27	Prepare room, equipment, supplies (select transducer, optimize gain, display, set sample volume, etc)	040	Vasc Tech	$ 0.540	3	3	4	4	3
28	Perform exam	040	Vasc Tech	$ 0.540	42	21	48	24	6
29	Collate preliminary data, arrange images, edit video tape	040	Vasc Tech	$ 0.540	10	8	10	6	7
30	Patient education/instruction/ counseling	040	Vasc Tech	$ 0.540	3	3	5	5	3
31	Coordinate home or outpatient care	040	Vasc Tech	$ 0.540	0	0	0	0	0
32	Clean room/equipment	040	Vasc Tech	$ 0.540	3	3	3	3	3
33	**Other Clinical Activity (please specify)**								
34	Patient history	040	Vasc Tech	$ 0.540	1	1	2	2	1
35	***End: Patient leaves office***								
36	**POST-SERVICE**								
37	**Post-Service Period Starts when patient leaves office**				Min	Min	Min	Min	Min
38	Phone calls, faxes, emails between visits with ordering physician, patient, family	040	Vasc Tech	$ 0.540	4	4	4	4	3
39	**Other Activity (please specify)**								
40	QA documentation	040	Vasc Tech	$ 0.540	4	4	4	4	3
41									
42	***End: When appointment for next study is made (if necessary)***								
43	**MEDICAL SUPPLIES**	Code	Unit	Unit Cost	QTY	QTY	QTY	QTY	QTY
44	patient gown, disposable	11107	item	$ 0.570	1	1	1	1	1
45	exam table paper	11111	foot	$ 0.015	7 feet	7 feet	7 feet	7 feet	7 feet
46	pillow case, disposable	11112	item	$ 0.320	1	1	1	1	1
47	paper towel	11118	item	$ 0.010	1	1	1	1	1
48	drape, sheet	11106	item	$ 0.260	1	1	1	1	1
49	patient ed. booklet (50% of the time)	11140	item	$ 0.460	1	1	1	1	1
50	gloves, non-sterile	11302	pair	$ 0.120	1	1	1	1	1
51	Transducer wipe (echo ultrasound)	11520	wipe	$ 0.094	2	2	2	2	2
52	aquasonic gel	71001	ml	$ 0.270	60 ml	60 ml	60 ml	60 ml	60 ml
53	film, 14x17	73402	sheet	$ 2.800	2	1	2	1	0
54	tape, VHS	73408	item	$ 3.000	1	1	1	1	0
55	recording paper	73414	sheet	$ 0.150	0	0	0	0	3
56	film, 8x10 color	73403	item	$ 0.850	3	2	3	2	0
57	Enviroside Cleanser	52302	10 ml	$ 0.340	10 ml	10 ml	10 ml	10 ml	10 ml
58									
59	**PROCEDURE SPECIFIC EQUIPMENT**								
60	Vascular Lab Room (=Ultrasound Room) Prices to be updated	E52018		$ 272.000	1	1	1	1	1
61	Stretcher	E11002		$2.664	1	1	1	1	1
62	Computer	E52003		$2.800	1	1	1	1	1
63	Processer	E51080			1	1	1	1	1
64	Viewbox, 2 panes	E51001			1	1	1	1	1
65	Sony Video Color Printer	E52010			1	1	1	1	1
66	SVHS Video Recorder	E53012			1	1	1	1	1
67									
68					93880	93882	93886	93888	93875
69	Original Consortium total time				88	62	97	68	40
70	Consortium Percentage				0.85	0.97	0.94	0.97	0.92
71	Consortium Contribution to new Total				74.8	60.14	91.18	65.96	36.8
72	Original ACR total time				62	43	62	43	43
73	ACR Percentage				0.15	0.03	0.06	0.03	0.08
74	ACR Contribution to new Total				9.3	1.29	3.72	1.29	3.44
75	New Total Time				84.1	61.43	94.9	67.25	40.24

Addendum C

ADDENDUM D

ICAVL STANDARDS FOR ACCREDITATION IN NONINVASIVE VASCULAR TESTING

PART I
VASCULAR LABORATORY OPERATIONS

ORGANIZATION

(This Standard applies to all applications.)

Introduction: A vascular laboratory is a unit performing noninvasive vascular diagnostic testing under the overall direction of a Medical Director. A Technical Director is appointed who is responsible for direct supervision of all of the technical staff and the daily operations of the laboratory.

Section 1 - Supervision and Personnel

STANDARD - Medical Director

1.1 A qualified Medical Director(s) must be designated for the facility.

Required Characteristics

1.1.1 Responsibilities:

1.1.1.1 The Medical Director is responsible for all clinical services provided and for the determination of the quality and appropriateness of care provided.

1.1.1.2 The Medical Director supervises the entire operation of the laboratory or may delegate specific operations to appropriate laboratory or administrative staff.

1.1.1.3 The Medical Director is responsible for the approval of medical staff members and the supervision of their work.

1.1.1.4 The Medical Director is responsible for maintaining and assuring compliance of the medical and technical staff to the standards outlined in this document.

Addendum D

1.1.2 Qualifications:

1.1.2.1 **The medical director must be a licensed physician and qualified to interpret studies.**

1.1.2.2 The medical director must demonstrate an appropriate level of training and experience by meeting one or more of the following:

A.) Formal Training Program – Completion of a residency or fellowship that includes appropriate didactic and clinical vascular laboratory experience as an integral part of the program. For those testing areas in which training is provided, the physician should have experience in interpreting the following minimum number of studies while under supervision:

Vascular Laboratory Examination	Minimum Number of Cases
• carotid duplex ultrasound	100 cases
• transcranial Doppler	100 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	100 cases
• peripheral arterial duplex ultrasound	100 cases
• venous duplex ultrasound	100 cases
• visceral vascular duplex ultrasound	75 cases

The formal training experience must be documented by a letter from the director of the training program verifying the areas of testing and the extent of the training and experience

B.) Informal (or self-study) training - Appropriate training and experience for proper qualifications to interpret noninvasive vascular laboratory studies can be achieved through formal accredited post-graduate education

A minimum of 40 hours of relevant Category I CME credit must be acquired within a three-year period. At least one half of these hours must be met with courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretation of the noninvasive vascular laboratory test the physician will interpret. The remaining hours may be dedicated to appropriate clinical topics relevant to vascular laboratory testing. Documentation of the CME courses with a listing of the content must be submitted

Comment: At least eight (8) of these hours must be applicable to each of the testing areas to be interpreted.

In addition to formal didactic studies, the physician must acquire a minimum of 8 hours of supervised practical experience observing or participating in testing procedures, preferably in an accredited laboratory, for each area of testing for which the physician will interpret. The practical experience must include all areas of testing for which the physician is applying. This experience must be documented with a letter from the Medical Director of the laboratory where the practical experience was obtained

For those examinations the physician will interpret, there must be documentation of interpretation for the following minimum number of studies while under the supervision of a physician who has already met the ICAVL criteria:

Vascular Laboratory Examination	Minimum Number of Cases
• carotid duplex ultrasound	100 cases
• transcranial Doppler	100 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	100 cases
• peripheral arterial duplex ultrasound	100 cases
• venous duplex ultrasound	100 cases
• visceral vascular duplex ultrasound	75 cases

C.) Established practice – Training and experience will be considered appropriate for a physician who has worked in a vascular laboratory for at least three years and has interpreted the following minimum number of vascular laboratory tests in the specific areas that will be interpreted:

Vascular Laboratory Examination	Minimum Number of Cases
• carotid duplex ultrasound	300 cases
• transcranial Doppler	300 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	300 cases
• peripheral arterial duplex ultrasound	300 cases
• venous duplex ultrasound	300 cases
• visceral vascular duplex ultrasound	225 cases

1.1.3 Continuing Medical Education

The Medical Director must show evidence of maintaining current knowledge by participation in CME courses that are relevant to vascular testing. To be relevant the course content must address the principles, instrumentation, techniques or interpretation of noninvasive vascular testing. A minimum of 15 hours of CME is required every three years, of which at least 10 hours are Category I. Laboratory correlation conferences or other internal quality assurance meetings are not to be counted as part of the CME requirement.

Comment: If the Medical Director has completed formal training as specified under 1.1.2.2(A) in the past three years, has successfully acquired an appropriate credential in vascular technology within the past three (3) years, or has begun new employment with the laboratory within one year prior to applying for accreditation, the CME requirement will be considered fulfilled.

STANDARD - Technical Director

1.2 A qualified Technical Director(s) must be designated for the facility.

Comment: The Medical Director or a member of the medical staff may serve as the Technical Director. That individual must satisfy the qualifications for Technical Director.

Required Characteristics

1.2.1 Responsibilities:

1.2.1.1 The Technical Director reports directly to the Medical Director.

1.2.1.2 Responsibilities include, but are not limited to, and may be delegated to other staff:

A.) All laboratory duties delegated by the Medical Director

B.) Supervision of the technical and ancillary staff

C.) Delegation, when warranted, of specific responsibilities to the technical staff and/or the ancillary staff

D.) Daily technical operation of the laboratory (e.g., staff scheduling, patient scheduling, laboratory record keeping, etc.)

E.) Operation and maintenance of laboratory equipment

F.) The compliance of the technical and ancillary staff to the standards outlined within this document

G.) Quality patient care

H.) Technical training

1.2.2 Qualifications

1.2.2.1 The Technical Director must have an appropriate credential in vascular testing.

1.2.2.2 For each testing area provided, the Technical Director must have performed the following minimum number of studies:

Vascular Laboratory Testing Areas	Minimum Number of Cases
• carotid duplex ultrasound	100 cases
• transcranial Doppler	100 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	100 cases
• peripheral arterial duplex ultrasound	100 cases
• venous duplex ultrasound	100 cases
• visceral vascular duplex ultrasound	75 cases

Comment: If the Technical Director does not meet the testing volume requirement for any of the testing sections, a qualified co-technical director is appointed for those testing sections.

1.2.3 Continuing Medical Education

The Technical Director must show evidence of maintaining current knowledge by participation in CME courses that are relevant to vascular testing. To be relevant the course content must address the principles, instrumentation, techniques or interpretation of noninvasive vascular testing. A minimum of 15 hours is required every three years. Laboratory correlation conferences or other internal quality assurance meetings are not to be counted as part of the CME requirement.

Comment: If the Technical Director has successfully acquired an appropriate credential in vascular technology within the past three (3) years, has successfully acquired an appropriate credential in vascular technology within the past three (3) years, or has begun

new employment with the laboratory within one year prior to applying for accreditation, the CME requirement will be considered fulfilled.

STANDARD - Medical Staff

1.3 Qualified medical staff are provided.

Required Characteristics

1.3.1 Responsibilities:

1.3.1.1 The medical staff interprets and/or performs clinical studies in accord with privileges approved by the Medical Director **and in compliance with the standards outlined in this document.**

1.3.2 Qualifications:

1.3.2.1 **Medical staff must be licensed physicians and qualified to interpret studies.**

1.3.2.2 The medical staff must demonstrate an appropriate level of training and experience by meeting one or more of the following:

A.) Formal Training Program – Completion of a residency or fellowship that includes appropriate didactic and clinical vascular laboratory experience as an integral part of the program. For those testing areas in which training is provided, the physician should have experience in interpreting the following minimum number of studies while under supervision:

Vascular Laboratory Examination	Minimum Number of Cases
• carotid duplex ultrasound	100 cases
• transcranial Doppler	100 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	100 cases
• peripheral arterial duplex ultrasound	100 cases
• venous duplex ultrasound	100 cases
• visceral vascular duplex ultrasound	75 cases

The formal training experience must be documented by a letter from the director of the training program verifying the areas of testing and the extent of the training and experience.

B.) Informal (or self-study) training - Appropriate training and experience for proper qualifications to interpret noninvasive vascular laboratory studies can be achieved through formal accredited post-graduate education

A minimum of 40 hours of relevant Category I CME credit must be acquired within a three-year period. At least one half of these hours must be met with courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretation of the noninvasive vascular laboratory test the physician will interpret. The remaining hours may be dedicated to appropriate clinical topics relevant to vascular laboratory testing. Documentation of the CME courses with a listing of the content must be submitted

Comment: At least eight (8) of these hours must be applicable to each of the testing areas to be interpreted.

In addition to formal didactic studies, the physician must acquire a minimum of 8 hours of supervised practical experience observing or participating in testing procedures, preferably in an accredited laboratory, for each area of testing for which the physician will interpret. The practical experience must include all areas of testing for which the physician is applying. This experience must be documented with a letter from the Medical Director of the laboratory where the practical experience was obtained

For those examinations the physician will interpret, there must be documentation of interpretation for the following minimum number of studies while under the supervision of a physician who has already met the ICAVL criteria:

Vascular Laboratory Testing Areas	Minimum Number of Cases
• carotid duplex ultrasound	100 cases
• transcranial Doppler	100 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	100 cases
• peripheral arterial duplex ultrasound	100 cases
• venous duplex ultrasound	100 cases
• visceral vascular duplex ultrasound	75 cases

C.) Established practice – Training and experience will be considered appropriate for a physician who has worked in a vascular laboratory for at least three years and has interpreted the following minimum number of vascular laboratory tests in the specific areas that will be interpreted:

Vascular Laboratory Examination	Minimum Number of Cases
• carotid duplex ultrasound	300 cases
• transcranial Doppler	300 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	300 cases
• peripheral arterial duplex ultrasound	300 cases
• venous duplex ultrasound	300 cases
• visceral vascular duplex ultrasound	225 cases

1.3.3 Continuing Medical Education

The medical staff must show evidence of maintaining current knowledge by participation in CME courses that are relevant to vascular testing. To be relevant the course content must address the principles, instrumentation, techniques or interpretation of noninvasive vascular testing. A minimum of 15 hours of CME is required every three years, of which at least 10 hours are Category I. Laboratory correlation conferences or other internal quality assurance meetings are not to be counted as part of the CME requirement.

Comment: If the medical staff member has completed formal training as specified under 1.3.2.2(A) in the past three years, has successfully acquired an appropriate credential in vascular technology within the past three (3) years, or has begun new employment with the laboratory within one year prior to applying for accreditation, the CME requirement will be considered fulfilled.

STANDARD - Technical Staff

1.4 Qualified technical staff are provided.

Required Characteristics

1.4.1 Responsibilities:

1.4.1.1 The technical staff reports to the Technical Director.

1.4.1.2 The technical staff assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical examinations and other tasks assigned.

1.4.2 Qualifications:

1.4.2.1 The technical staff must have an appropriate level of training, technical certification or documented experience.

1.4.2.2 The technical staff must demonstrate an appropriate level of training and experience by meeting one or more of the following criteria:

A.) **Credential:** An appropriate credential in vascular testing

B.) **Formal Ultrasound training:** Successful completion of an ultrasound, vascular technology or cardiovascular technology program that includes verified didactic and supervised clinical experience in vascular testing. The program should be accredited by either the Joint Review Committee on Education in Diagnostic Medical Sonography (JRC-DMS), the Joint Review Committee on Education in Cardiovascular Technology (JRC-CVT), or the Canadian Medical Association (CMA)

C.) **Post secondary education plus experience:** 12 months full time (at least 35 hours/week) clinical vascular testing experience plus one of the following:

1) Completion of a formal two-year program or equivalent in another allied health profession

2) Completion of a bachelor's degree unrelated to vascular technology

3) A MD or DO degree

D.) **Experience only:** A minimum of 12 months of vascular testing practice experience with the performance of at least 600 noninvasive vascular examinations under the supervision of medical or technical staff who meet the above criteria. The noninvasive vascular examinations performed by these technical staff members must be appropriately distributed among the testing areas performed within the laboratory

Note: An individual who does not meet at least one of the above is considered a "trainee."

1.4.2.3 For those testing areas in which the testing is provided, the technical staff member must have performed the following minimum number of studies:

Vascular Laboratory Examination	Minimum Number of Cases
• carotid duplex ultrasound	100 cases
• transcranial Doppler	100 cases
• peripheral arterial physiologic tests (e.g. extremity pressures, Doppler waveforms, exercise testing, reactive hyperemia)	100 cases
• peripheral arterial duplex ultrasound	100 cases
• venous duplex ultrasound	100 cases
• visceral vascular duplex ultrasound	75 cases

Comment: An individual who does not meet this requirement is considered a trainee in any testing area in which this minimum case requirement is not fulfilled.

1.4.3 Continuing Medical Education

The technical staff must show evidence of maintaining current knowledge by participation in CME courses that are relevant to vascular testing. To be relevant the course content must address the principles, instrumentation, techniques or interpretation of noninvasive vascular testing. A minimum of 15 hours is required every three years. Laboratory correlation conferences or other internal quality assurance meetings are not to be counted as part of the CME requirement.

Comment: If the technical staff member has successfully acquired an appropriate credential in vascular technology within the past three (3) years, or has begun new employment with the laboratory within one year prior to applying for accreditation, the CME requirement will be considered fulfilled.

STANDARD - Trainees

1.5 Training, if conducted, does not compromise patient care and benefits the trainee.

Required Characteristics

1.5.1 Supervision:

1.5.1.1 The Medical Director must ensure that the responsibilities assumed by the trainee are appropriate. Trainees perform/interpret procedures only with direct medical and/or technical staff supervision.

Section 2 - Support Services

STANDARD - Support Services

2.1 Ancillary personnel (clerical, nursing, transport, etc.) necessary for safe and efficient patient care are provided.

Required Characteristics

2.1.1 Supervision:

2.1.1.1 The Medical Director must ensure that support services appropriate and in the best interest of patient care are provided.

2.1.2 Support Services:

2.1.2.1 Clerical and administrative support must be sufficient to ensure efficient operation and record keeping.

2.1.2.2 Nursing and ancillary services sufficient to ensure quality patient care are available when necessary.

Section 3 - Physical Facilities

STANDARD - Examination Areas

3.1 Examinations must be performed in a setting providing patient and technical staff safety, comfort and privacy.

STANDARD - Interpretation Space

3.2 Adequate designated space must be provided for the interpretation of examination results and preparation of reports.

STANDARD - Storage Space

3.3 Adequate designated space must be provided for the convenient storage of supplies, records and reports.

Section 4 - Examination Interpretation, Reports, and Records

STANDARD - Examination Interpretation and Reports

4.1 Noninvasive vascular examinations are interpreted and reported by the Medical Director or a member of the medical staff of the vascular laboratory.

Comment: The report represents the final interpretation of the noninvasive vascular examination and is part of the patient's legal medical record. As such, the report must be in the form of a document that is retrievable and/or reproducible for review by health care personnel. In general, the report must contain information such that a health care professional whom may previously have been unfamiliar with the case is provided adequate information regarding the indications for the examination, the type of examination performed and the results of the diagnostic study.

Required Characteristics

4.1.1 All reporting must be standardized in the laboratory. All physicians interpreting noninvasive vascular examinations in the laboratory must agree on and utilize uniform diagnostic criteria and a standardized report format.

4.1.2 Interpretation must include review of all examination data including measurements, images, and recordings by the Medical Director or a member of the Medical Staff.

4.1.3 The report must accurately reflect the content and results of the examination.

4.1.4 Final report must be verified and signed by the Medical Director or a member of the medical staff of the laboratory.

4.1.5 The final report must be typed and must include, but is not limited to:

4.1.5.1 The date of the examination

4.1.5.2 The clinical indications leading to the performance of the examination

4.1.5.3 An adequate description of the test performed: the description must include the name of the examination and its integral parts (e.g. noninvasive arterial examination of the lower extremities with segmental pressures and volume plethysmography)

4.1.5.4 Description of pertinent positive and negative findings: disease, if present, must be characterized according to its location, extent and severity and incidental findings should be reported

4.1.5.5 The reasons for technically limited, suboptimal or incomplete examinations

4.1.5.6 A summary (impression/conclusion) of the test findings. Whenever appropriate the final interpretation should address the clinical indications for the study

4.1.5.6 Comparison with previous related studies where available

4.1.5.7 Typed name and signature and/or electronic verification

Comment: The use of signature stamps is strongly discouraged. The use of signature stamps provides the potential for inappropriate use by personnel other than the physician whose signature appears on the stamp.

4.1.5.8 Date of interpretation, signature or verification

4.1.6 If preliminary findings are provided, their preliminary nature must be clearly indicated. A mechanism for communicating any significant changes must be defined for those situations in which the final interpretation differs substantially from the preliminary findings.

4.1.7 A mechanism must be defined whereby the results of examinations that demonstrate urgent or life threatening findings are communicated to the appropriate health care professionals in a timely fashion.

4.1.8 The physician interpretation must be available within two (2) working days of the examination.

Comment: An interpretation can be in the form of paper, digital storage or voice system. The final verified signed report must be available in a timely fashion, generally within 4 working days.

STANDARD - Records

4.2 Provisions exist for the generation and retention of examination records of all studies performed.

Required Characteristics

4.2.1 Essential portions of all examinations must be documented on appropriate media. This may include printed, photographic and/or electronic media, hard copy and video documenting images, waveforms, and audio/video recordings of representative portions of the examinations and printed documentation of measurements.

4.2.2 A complete and accurate final report including signature must be generated as outlined in Section 4.1, as part of the record of the examination.

4.2.3 Identification of the technologist(s) performing the vascular examination must appear as a part of the permanent record.

4.2.4 All records of the examination, including a signed, dated final report, as outlined in Sections 4.1 and 4.2, **must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years for adult patients.**

Section 5 - Miscellaneous

STANDARD - Patient Safety

5.1 Patient safety is ensured by written policies and procedures approved by the Medical Director.

Required Characteristics

5.1.1 A procedure must exist for identification of patients who suffer untoward effects or complications of studies performed and a permanent record of such is maintained.

5.1.2 Procedures and policies must exist with respect to control of infectious diseases, transducer cleaning and protection of laboratory personnel from the transmission of infectious diseases and blood borne pathogens.

5.1.3 A policy must be in place for handling acute medical emergencies, and appropriate equipment, supplies, and trained personnel must be available to deal with medical emergencies and critically ill patients.

5.14 A policy must exist regarding routine inspection and testing for electrical safety of all existing equipment.

5.1.5 The laboratory must meet the standards set forth by the Occupational Safety and Health Administration (OSHA) and by The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), where applicable.

STANDARD - Patient Confidentiality

5.2 All laboratory personnel must ascribe to professional principles of patient-physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

Section 6 - Quality Assurance and Quality Control

STANDARD - Quality Assurance

6.1 There must be a written policy regarding quality assurance for all procedures performed in the laboratory.

Required Characteristics

6.1.1 Regular Ongoing quality assurance must be performed for all areas of vascular testing performed by the laboratory as outlined in the standards specific to that area.

6.1.2 A minimum of two vascular laboratory quality assurance conferences per year must be held to review the results of comparative studies, address discrepancies and to discuss difficult cases and laboratory issues and minutes maintained.

STANDARD - Quality Control

6.2 Instrumentation used for diagnostic testing must be maintained in good operating condition.

Comment: The accuracy of the data collected by ultrasound instruments is paramount in the interpretation and diagnostic utilization of the information collected.

Required Characteristics

6.2.1 Guidelines for equipment maintenance include, but are not limited to, the following:

6.2.1.1 Recording of the method and frequency of maintenance of ultrasound instrumentation and non-imaging equipment.

6.2.1.2 Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.

6.2.1.3 Establishment of and adherence to an instrument cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to the specifications of the manufacturer. The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

Section 7 – Multiple Sites and Mobile Services

Standard – Multiple Sites

7.1 When testing is performed at more than one physical facility, the laboratory may be eligible to apply for a single accreditation as a multiple site laboratory.

Required Characteristics

7.1.1 All facilities have the same Medical Director

7.1.2 All facilities are supervised by the same Technical Director

Comment: Supervision may be accomplished by one or more of the following:

A) The Technical Director works at each site two days each month

B) Every Technical Staff member from each of the satellite laboratories works at the main laboratory two days each month

C) An appropriately credentialed lead technologist is appointed at each satellite laboratory to report to the Technical Director
The lead technologist:

a. Supervises and assists others in performing exanimations
b. Oversees day to day activities in the satellite laboratory
c. Communicates weekly with the Technical Director to maintain compliance with the testing standards

7.1.3 Identical testing protocols are used at all sites

7.1.4 Identical diagnostic criteria are used at all sites

7.1.5 Quality assurance must be evaluated for each site for all areas of testing performed at the site

7.1.6 Equipment of similar quality and capability must be used at all sites

Standard – Mobile Service

7.2 A mobile service is comprised of one or more units (technologist and equipment) that provide vascular testing services at one or more locations.

Comment: Some laboratories provide only mobile services and do not have a primary site laboratory. These mobile service laboratories are required to complete the entire accreditation application.

Required Characteristics

7.2.1 The entire mobile service has the same Medical Director.

7.2.2 The entire mobile service is supervised by the Technical Director who is responsible for ongoing evaluation of the technical component of the testing performed by the mobile service.

7.2.3 All mobile vascular examinations are interpreted by medical staff included in the application

7.2.4 All mobile vascular examinations are performed by technical staff included in the application

7.2.5 Equipment of similar quality and capability must be used for all mobile testing.

Comment: If the mobile service is a component of a primary site laboratory, the equipment used by the mobile service must the of similar quality and capability of the equipment used in the primary site.

7.2.6 The entire mobile service utilizes identical protocols.

7.2.7 The entire mobile service utilizes identical diagnostic criteria.

7.2.8 Quality Assurance must be evaluated for testing performed by the mobile service.