



Coalition For Quality In Ultrasound

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September 3, 2004

Medicare Payment Advisory Commission (MedPAC)
601 New Jersey Avenue, N.W.
Suite 9000
Washington, D.C. 20001

Re: Ultrasound Credentialing and Accreditation - Necessary Means of
Ensuring the Appropriate Utilization of Diagnostic Ultrasound Services

Dear Commission Members:

The Coalition for Quality in Ultrasound (“CQU”) shares MedPAC’s concern about the increase in the utilization of imaging services that has occurred over the past few years. We believe that the causes of this increase are complicated. Accordingly, CQU appreciates this opportunity to offer its assistance in evaluating the means by which the federal government can promote appropriate utilization and control costs while ensuring the accessibility of high-quality, medically necessary health care services. To that end, the members of CQU are confident that the adoption of a credentialing and/or accreditation standard as a condition for Medicare coverage of diagnostic ultrasound services will advance our common objective of achieving cost-effective, high-quality care for Medicare beneficiaries. We would like to meet with you to discuss our perspective further.

CQU is committed to the implementation of nationwide accreditation and/or credentialing requirements for Medicare reimbursement of all ultrasound services. Active members of CQU include: the American College of Radiology, American Institute of Ultrasound in Medicine, American Registry of Diagnostic Medical Sonographers, Cardiovascular Credentialing International, Intersocietal Commission for the Accreditation of Echocardiography Laboratories, Intersocietal Commission for the Accreditation of Vascular Laboratories, Joint Review Committee on Education in Diagnostic Medical Sonography, Society of Diagnostic Medical Sonography, Society of Interventional Radiology, Society for Vascular Surgery, and the Society for Vascular Ultrasound. The research, experience and expertise of CQU’s diverse constituents have demonstrated that appropriate utilization of ultrasound services, and the protection of the Medicare program and of Medicare beneficiaries, can best be achieved and maintained by requiring the credentialing of the non-physician personnel performing the technical component of the services and/or the accreditation of the laboratories in which the services are provided.

Credentialing is a process by which the individual who acquires the data that constitutes the technical component of an ultrasound study undertakes an examination designed to ensure that this individual has documented sufficient skills, knowledge, and education to

perform this function. National organizations sponsored by the relevant clinical organizations have established widely-regarded credentialing programs. The competence of the person performing the service is critical, as a lack of the appropriate skills, knowledge, and education can lead to a multitude of errors that directly impact appropriate utilization, patient care and safety. For example, the incorrect positioning of the transducer used to direct the sound waves that acquire the data will often lead to incorrect images, or missing images, or other data being acquired, which can have a variety of detrimental effects on a patient. Credentialing is offered separately in each of the distinct areas of ultrasound. Though there are substantial differences in the scope of particular credentials, the three basic areas of ultrasound are echocardiography (involving studies of the heart), vascular (involving studies of the venous and arterial system), and general ultrasound (all other studies).

During the accreditation process, the focus is on the laboratory in which the ultrasound is provided, including both fixed and mobile laboratories. Every aspect of the laboratory's operation is scrutinized to determine its potential impact on patients. Accreditation generally involves a detailed self-evaluation by the laboratory and its vascular technologists or sonographers as well as a comprehensive, confidential review of that evaluation by representatives of the accreditation program. In addition to evaluating the credentials of the individuals performing the scans, physicians interpreting the images also must meet specific criteria; sites must have quality assurance, quality control and safety protocols in place; and, finally, the quality of the actual patient exams are evaluated. Furthermore, accreditation must be renewed on a regular basis, which not only creates a long-term incentive for personnel to develop appropriate goals but also demonstrates a commitment by the laboratory to achieving the highest standards of patient care.

The need for credentialing and/or accreditation requirements is underscored by:

- (i) The consensus of essentially every relevant vascular and ultrasound-related medical society and organization, and a growing number of Medicare carriers in thirty-eight (38) states, that the requirement is essential to ensure that patients receive, and that Medicare pays for, only those studies that meet certain minimum standards of quality assurance;
- (ii) The threat to the integrity of the Medicare program, and to the care of Medicare beneficiaries, when ultrasound services are provided by uncredentialed technologists or sonographers and unaccredited laboratories;
- (iii) The frequent use of an accreditation or credentialing standard in the Medicare program as the principal means of controlling inappropriate utilization and of ensuring the highest quality of care; and
- (iv) The documented availability of accredited laboratories and credentialed vascular technologists and sonographers.

In light of the above, CQU has developed language for a model Local Coverage Determination ("LCD") (formerly referred to as a Local Medical Review Policy ("LMRP")) on vascular and general ultrasound studies to be used by local Medicare carriers (or Medicare Administrative Contractors ("MACs")). CQU also has endorsed the attached model echocardiography policy of the American Society of Echocardiography. CQU urges MedPAC to consider the value of the accreditation and/or credentialing standards articulated in these model policies when advising Congress on appropriate utilization and other Medicare policy issues.

We believe that MedPAC should encourage Congress to adopt a statutory requirement under Medicare consistent with these policies.

CQU appreciates MedPAC's role in advising Congress about this critical issue. We hope that the information provided below will be of assistance to that end.

I. The Overwhelming Consensus Among Providers and Medicare Carriers Is That a Credentialing and/or Accreditation Requirement Should Be a Condition of Medicare Coverage for a Variety of Studies

A. Consensus Among Ultrasound Providers

Each of CQU's members represents an important voice in ultrasound services. Significantly, all of them believe that accreditation and/or credentialing requirements are necessary to promote the appropriate utilization of ultrasound services and to protect the interests of the Medicare program and its beneficiaries.¹ A brief description of the active members in the CQU is attached. As is clear from the discussion of our members and their constituencies, the CQU represents a clear consensus among relevant medical professionals, societies and organizations that the credentialing of non-physician personnel and/or the accreditation of laboratories should be a condition for Medicare coverage of ultrasound studies.

B. Consensus Among Many Medicare Carriers

The sentiment of the medical community is reinforced by a national consensus among Medicare carriers regarding the importance of a credentialing and/or accreditation requirement. At present, at least 38 states have implemented or recommended directives that incorporate this standard for Medicare reimbursement of various types of ultrasound studies. The growing trend among carriers in establishing these requirements is in accordance with CMS' directive to make LCDs as consistent as possible from jurisdiction to jurisdiction. We provide a list of the applicable LCD provisions in Exhibit 1 to this letter.

We note that the authority of carriers to institute requirements, such as personnel credentialing and/or laboratory accreditation, is clear. The Social Security Act states that no payment may be made for services that are not "reasonable" and "necessary" for the diagnosis and treatment of an illness or injury.² CMS has very broad authority in determining what qualifies as "reasonable" and "necessary," and has used this authority in many situations that are analogous to the accreditation or credentialing standards issued by carriers in connection with vascular ultrasound and other ultrasound studies.

Furthermore, CMS has stated that, in the absence of a specific national coverage determination, coverage decisions are to be made at the discretion of the local contractors.³ As such, where CMS has not issued a national coverage determination, the decision of whether accreditation or credentialing should be required under the "reasonable" and "necessary" standard falls to the carriers. In connection with this, we note that the contract between the Medicare program and the carriers requires the carriers to institute safeguards that include

¹ The CQU recommends accreditation and credentialing as a standard requirement when both are available. If undue hardship, due to geographic or other factors, prevents accreditation and credentialing requirements, then credentialing is recommended as a minimum requirement.

² Section 1862(a)(1)(A).

³ See 64 Fed. Reg. at 22621 (April 27, 1999).

methods of ensuring that payments for covered services are medically necessary.⁴ This requirement of safeguards was a strong factor in the emergence of so many credentialing or accreditation LCDs.

Significantly, CMS has itself endorsed credentialing as a means of ensuring that appropriate services are performed. By regulation, CMS has required Independent Diagnostic Testing Facilities, those diagnostic laboratories that are not a part of a physician practice or a hospital, to use persons credentialed by a national credentialing organization when providing Medicare services in the absence of state licensure. There is no state licensure in any jurisdiction for ultrasound, a fact that underscores the need for the quality measures discussed in this letter. We have attached the relevant portion of this rule as Exhibit 2.

Despite the progress that has been made under existing law in establishing credentialing or accreditation standards, there are still, unfortunately, many jurisdictions and services that are not covered by these standards. It is for this reason that Congressional action is needed.

II. A Credentialing and/or Accreditation Requirement Is Critical to Ensuring That the Medicare Program Is Not Subjected to Inappropriate Services That Threaten the Welfare of Medicare Beneficiaries

Significant problems have consistently emerged in states that lack LCDs with a credentialing and/or accreditation standard. These problems include discrepancies in testing results between qualified (i.e., laboratories that are accredited or that use credentialed personnel) and unqualified providers,⁵ along with the concomitant time, expense, and inefficiency of repeating unqualified studies and having incorrect treatment decisions based on incorrect test results.

Physicians must depend on the results of noninvasive studies to make accurate diagnoses and to implement appropriate treatment plans for patients. As noted above, ultrasound studies are highly “operator dependent,” reflecting the need for broad based knowledge, good judgment, and discretion by the technologist or sonographer who acquires the images and the data and the physician who interprets the studies. Very often, the results of a non-invasive examination will determine whether major surgery or medical treatment is recommended to a Medicare patient. For instance, a high-quality vascular laboratory that is accredited and/or that employs credentialed personnel may well enable vascular surgeons to forego the use of angiography for patients who are undergoing carotid endarterectomy. The provision of high quality vascular ultrasound studies thereby has become essential to the current practice of vascular surgery. These noninvasive vascular studies have contributed to significant reductions, in terms of costs to the Medicare program and with respect to patient morbidity and mortality, due to the risks that are inherent in angiography. By contrast, the organizations that support this letter, and the empirical data that they have collected, confirm that they routinely receive orders to perform repeat studies that were initially performed unsatisfactorily by a technologist or sonographer who was not credentialed and/or in a laboratory that lacked accreditation. Those original studies are often incorrect or incomplete.

⁴ Article XII, Part B Medicare Contract.

⁵ The carotid is the main mechanism by which the brain receives its blood supply and, therefore, carotid studies are a critical service in assessing stroke issues in patients.

Moreover, there is compelling evidence that critically important diagnoses are being missed and that “false positives” are being identified by unaccredited laboratories using uncredentialed personnel. These errors have significant consequences, as a misdiagnosis can lead, for instance, to a stroke or even death. As was discussed above, the fact that a clear and increasing number of Medicare carriers already have implemented requirements for Medicare reimbursement of non-invasive vascular studies is further evidence that these problems occur with regularity and are widespread, yet can be effectively addressed by requiring that vascular technologists or sonographers be credentialed and/or that vascular laboratories be accredited as a condition of Medicare reimbursement. By implementing a technologist or sonographer credentialing and/or laboratory accreditation standard, carriers have furthered the clearly articulated interests of CMS and Congress in developing quality of care initiatives and in avoiding these medical errors.

Finally, peer-reviewed studies and journal articles support the significance of implementing a credentialing and/or accreditation requirement to mitigate the risk of the aforementioned medical errors and to improve the quality of patient care. We have enclosed a small sample of these studies/articles for your review.

In one study conducted in Royal Oak, Michigan, researchers at Beaumont Hospital compared the quality and reliability of extracranial carotid artery duplex ultrasound examinations performed by an unaccredited vascular laboratory with repeat examinations performed in the Beaumont laboratory, which holds ICAVL accreditation. The results of the study were published in the *Journal of Vascular Surgery* (“JVS”) in an article entitled, “Reliability of Extracranial Carotid Artery Duplex Ultrasound Examinations: Value of Vascular Laboratory Accreditation,” authored by O. William Brown, M.D., *et. al.*

The objective of the study reported in this article was to evaluate the reliability of carotid duplex ultrasound testing performed by unaccredited vascular laboratories and to assess the clinical impact on patient management. The study found that of the 174 patients referred for surgical evaluation for carotid endarterectomy, 88 patients (51%) were found to have less than the 60% percent or higher stenosis that had been diagnosed by unaccredited vascular laboratories. The overestimation of stenosis by the unaccredited laboratory was attributed to technical errors (19 arteries), use of B-mode image data alone without the use of velocity criteria for confirmation of the lesion (36 arteries), and use of inappropriate velocity criteria (49 arteries). Because of the study, more than half of all patients who participated in this sub-group were spared the risks of an unnecessary surgery to “correct” a condition that did not exist.⁶

Additionally, for nineteen (19) patients who were diagnosed by unaccredited vascular laboratories to have a less than 60% diameter stenosis, a repeat study by an accredited vascular laboratory, in fact demonstrated a greater than 60% diameter stenosis. All of these patients subsequently underwent an uncomplicated carotid endarterectomy, which provided them with a statistically significant chance of decreasing their risk of stroke. The medical mismanagement resulting from the original study would have gone unnoticed if the patients’ carotid duplex ultrasound study had not been repeated, and the degree of stenosis accurately determined, by a qualified facility.

The article concludes that results of carotid duplex ultrasound studies from unaccredited laboratories should be considered with “extreme caution and do not appear reliable” in planning treatment of patients with obstructive disease. This finding is significant because in

⁶ Correlating data in all patients with a subsequent evaluation (angiography, MRA, or surgery) supported the findings of the accredited laboratories.

modern clinical practice, carotid duplex ultrasound is increasingly the sole diagnostic study that is conducted prior to the performance of surgical intervention with carotid endarterectomy.

These findings also were corroborated by another peer-reviewed study conducted by David Stanley, M.D., a vascular surgeon who is employed by an ICAVL-accredited facility in Tennessee. This study used standard criteria to compare the results of a repeat vascular study performed by Dr. Stanley's laboratory to the results of studies that were initially performed by accredited and unaccredited laboratories. The findings of the study indicated an 83% correlation rate to studies that were initially performed at accredited laboratories. However, when the initial study was performed by a laboratory that was not accredited, the correlation rate fell to 45%, indicating that these studies were more often than not incorrect. This study was published in the June 2004 issue of SVU's *Journal for Vascular Ultrasound* ("JVU"), a highly-respected, peer-reviewed medical journal, which consists of original scientific and educational articles, case studies, book reviews, technical reviews, ultrasound principle reviews, viewpoints, letters to the editor, and CME tests.⁷

Another study, which was conducted by SVU and SDMS in 2003, resulted in similar findings. This study involved a survey of vascular technologists and sonographers in Indiana and Kentucky.⁸ The study found that an average of 12% of all carotid duplex exams (a total of 4,872 in this study) were repeatedly annually due to errors that were attributable to the absence of a credentialing or accreditation requirement. The investigators commented that the 12% estimate represents the "lucky" patients, because that figure does not include all of the "disturbingly high" instances in which defective studies were performed and relied upon in determining the course of treatment. The study documented other adverse effects of poor studies, including instances of a false positive, missed diagnoses, and false negatives.

The study concluded that defective studies performed in unaccredited laboratories or by uncredentialed personnel are routinely responsible for patients undergoing such invasive procedures, with their attendant risks, as angiography and carotid endarterectomy. The situation is particularly acute in the context of vascular ultrasound services because the decision to perform these invasive surgeries is based, solely or principally, upon an abnormal carotid duplex scan. Fifty-seven percent of members surveyed reported that discrepancies in exams are found either "very often" or "often." A variety of reasons were given for repeat exams, the majority of which related to inadequate diagnostic criteria, failure to adhere to diagnostic standards, incomplete physician interpretation, and incompetent technical staff.

The findings of this study were published in the November/December 2003 issue of the *Journal of Diagnostic Medical Sonography* ("JDMS") in an article entitled, "Practice Patterns and Membership Opinion About the Value of Credentialing and Accreditation: Results of a Membership Survey." More than 14,000 sonographers subscribe to *JDMS*, which has been the premier journal for sonographers since 1976. The journal publishes peer-reviewed articles, case studies, and forums related to sonography practice in vascular, cardiology, obstetrics, pediatrics, and general medicine settings. All manuscripts submitted to *JDMS* are peer-reviewed by experts representing all ultrasound specialties, and the editorial board is composed of eminent sonographers, physicians, and physicists. The overall acceptance rate for manuscripts is 46%. *JDMS* is abstracted or indexed in Cumulative Index to Nursing and Allied Health Literature ("CINAHL"), Current Contents, and EMBASE/Excerpta Medica. The journal contents also are

⁷ More information about *JVU* and the editorial process may be found at the *JVU* website: <http://www.svunet.org/JVU/>.

⁸ One hundred SVU and SDMS members were surveyed. There was a thirty percent return rate, which is comparable to the return rate that CMS uses in surveys.

available on the Internet through several intermediaries.⁹ SVU also published an article on this study in the December 2003 issue of the aforementioned *JVU* entitled, "A Case Study of the Value of Society for Vascular Ultrasound Membership Participation in Defining Local Medical Review Policy: Results of an Indiana and Kentucky Practice Survey."

The above studies and articles reinforce the clear, negative impact on patient management that results from the failure to require the use of an accredited laboratory and/or credentialed personnel. Additionally, the substantial financial impact borne by the Medicare program cannot be ignored. The key to preventing these problems is through sonographer and vascular technologist credentialing and/or laboratory accreditation.

III. Use of an Accreditation and/or Credentialing Requirement Is a Common and Appropriate Way to Ensure Medically Necessary Care Under the Medicare Program

There are many examples of CMS, or its contractor carriers, requiring or permitting either the credentialing and/or accreditation of providers as a prerequisite to participating in the Medicare program.

As noted above, CMS recognizes the effectiveness of these measures to control inappropriate utilization in diagnostic services, including ultrasound. Throughout the regulations, there are requirements for completion of provider training programs that must be accredited by a national accreditation body.¹⁰ For example, as discussed above, Independent Diagnostic Testing Facilities ("IDTFs") are required to ensure that non-physician personnel who perform tests are certified by an appropriate national credentialing body in the absence of state licensure.¹¹ In addition, Medicare coverage of the services provided by physician assistants requires that they pass the national certification examination administered by the National Commission on Certification of Physician Assistants ("NCCPA").¹² Furthermore, Medicare requires that Clinical Nurse Specialists become certified by the American Nurses Credentialing Center.¹³

Other examples of plans that have imposed credentialing or accreditation requirements include: Blue Cross Blue Shield of North Carolina's mandate that all centers performing stress echocardiograms be accredited by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories ("ICAEL") by January 1, 2003; HGSAdminstrators' (Northeast Region) requirement of certification of sonographers and facility accreditation for procedures such as bladder capacity ultrasounds; HGSAdminstrators Pennsylvania's requirement that physician assistants pass the national certification examination administered by NCCPA; and Nationwide Medicare's (Ohio and West Virginia) requirement that freestanding facilities that perform sleep studies be certified by the American Sleep Disorders Association and have an accredited Clinical Polysomnographer on staff.

⁹ Additional information about *JDMS*, including its editorial board, may be found at the *JDMS* website: <http://www.sdms.org/jdms/default.asp>.

¹⁰ See *e.g.*, 42 C.F.R. § 485.70 (respiratory therapist and respiratory therapy technician); 42 C.F.R. § 460.64 (physical therapist and occupational therapist); 42 C.F.R. § 486.104 (portable X-ray technologist).

¹¹ 42 C.F.R. § 410.33(c).

¹² 42 C.F.R. § 410.74(C)(2).

¹³ 42 C.F.R. § 410.76.

IV. Credentialed Personnel and Accredited Facilities Are Widely Available

The implementation of study reimbursement directives by thirty-eight states has increased the demand for, and the supply of, credentialed personnel and accredited facilities. Although these policies have led to the introduction of accreditation and/or credentialing standards in many diverse communities, there has never been a single case in which access to services was denied because of the requirement. Accreditation and/or credentialing requirements are not difficult to satisfy, as they typically are drafted to require as a condition of Medicare coverage either the credentialing of the vascular technologist or sonographer or the accreditation of the laboratory, which gives providers an opportunity to choose which path to pursue to achieve compliance. Laboratory accreditation, it should be noted, does not even require a minimum number of studies to proceed through the process. Again, the critical point to emphasize is that no access difficulties have been reported in any of the states where accreditation or credentialing policies have been required or recommended, even in states that have significant concentrations of rural communities.

It also should be emphasized that credentialing requirements do not improperly regulate or restrict the ability of physicians to perform non-invasive vascular studies. If a physician performs the technical component service himself or herself, there is no restriction on his or her ability to provide that service. Instead, credentialing requirements constitute a reasonable and appropriate restriction on non-physician personnel who provide technical component services. Since there is no state that licenses non-physician personnel who provide studies, credentialing is the only means to ensure the minimum competence of that person. Furthermore, because most state requirements offer an option of credentialing or accreditation, any restriction on personnel can be eliminated by opting for accreditation.

V. CQU's Model Policy

Although there is some variation in the policies adopted by the many carriers that impose an accreditation and/or credentialing requirement for different services, the provisions generally require that studies be performed either by a credentialed sonographer or technologist or in a laboratory that is accredited. A model policy for vascular ultrasound is attached. This policy is typical of the LCDs of carriers that have implemented an accreditation and/or credentialing requirement. While minor revisions have been made in order to permit a more flexible transition, we note that our member organizations generally do not support transition periods of more than three years for urban areas or four years for rural areas.

VI. Conclusion

Given the consensus of medical opinion and the empirical evidence that supports a credentialing and/or accreditation standard with respect to non-invasive studies, we encourage MedPAC to recommend to Congress the development and adoption of accreditation and/or credentialing standards in ultrasound as a means of ensuring appropriate utilization. The value of a credentialing and/or accreditation standard as a condition of Medicare coverage of diagnostic ultrasound services is clear, as is the cost to Medicare and the danger to Medicare beneficiaries of permitting uncredentialed personnel and/or unaccredited facilities to provide these services. Thus, accreditation and/or credentialing standards are essential to achieving our

shared goal of ensuring that Medicare beneficiaries receive appropriate, cost-effective care of the highest quality.

Thank you for your consideration. Please contact the Coalition for Quality in Ultrasound if we can provide further information or assistance.

Sincerely,

On behalf of the Coalition for Quality in Ultrasound:

American College of Radiology
American Institute of Ultrasound in Medicine
American Registry of Diagnostic Medical Sonographers
Cardiovascular Credentialing International
Intersocietal Commission for the Accreditation of Echocardiography Laboratories
Intersocietal Commission for the Accreditation of Vascular Laboratories
Joint Review Committee on Education in Diagnostic Medical Sonography
Society of Diagnostic Medical Sonography
Society of Interventional Radiology
Society for Vascular Surgery
Society for Vascular Ultrasound

- The American College of Radiology (“ACR”) is a non-profit, professional association representing over 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. A recognized leader in accreditation programs, the ACR is dedicated to advancing the science of radiology and improving the quality of patient care. The ACR ultrasound accreditation program was established in 1995 and includes general ultrasound, obstetrics, gynecological and vascular ultrasound modules. Designed with a focus on education, the ACR ultrasound accreditation program provides a comprehensive review and evaluation of a facility as the program evaluates qualifications of personnel (both physician and non-physician), equipment performance, effectiveness of quality assurance/control measures, safety protocols, and the quality of images. The ACR programs recognize the importance of personnel certification and require that all sonographers be certified. If the facility provides vascular ultrasound services, at least one technologist must be certified as a Registered Vascular Technologist (“RVT”) by the ARDMS, a Vascular Sonographer (“VS”) by the ARRT, or as a Registered Vascular Specialist (“RVS”) (formerly known as “RCVT”) by Cardiovascular Credentialing International (“CCI”). Physician training and continuing education requirements are also defined. Please see the attached information on the ACR accreditation program.
- The American Institute of Ultrasound in Medicine (“AIUM”) is a multidisciplinary organization, which advances the art and science of ultrasound in medicine and research through educational, scientific, literary and professional activities. AIUM's Ultrasound Practice Accreditation Council has developed standards for the accreditation of ultrasound practices that serve as a benchmark for ultrasound professionals seeking to meet nationally accepted protocols.

- The American Registry of Diagnostic Medical Sonographers (“ARDMS”) is an independent nonprofit organization that for 29 years has awarded credentials to ultrasound professionals through examinations. Widely respected for its high standards by the medical community, ARDMS offers certification in three ultrasound clinical specialties: Registered Diagnostic Medical Sonographer (“RDMS”), Registered Diagnostic Cardiac Sonographer (“RDCS”), and Registered Vascular Technologist (“RVT”). ARDMS has over 44,000 actively certified ultrasound professionals. Please see the attached information on the ARDMS credentialing program.
- Cardiovascular Credentialing International (“CCI”) is an independent nonprofit organization that awards credentials to cardiovascular technology professionals through credentialing examinations. CCI is the resultant corporation of the merger of the original credentialing bodies in the field of Cardiovascular Technology, with the first credentials awarded in 1968. CCI administers credentials in four cardiovascular technology specialties: Certified Cardiographic Technician (“CCT”), Registered Cardiovascular Invasive Specialist (“RCIS”), Registered Cardiac Sonographer (“RCS”), and Registered Vascular Specialist (“RVS”). In CCI’s 30+ year history, individuals from over 20 countries have earned CCI credentials. Please see the attached information on the CCI credentialing program.
- The Intersocietal Commission for the Accreditation of Echocardiography Laboratories (“ICAEL”) provides a laboratory peer-review evaluation program to ensure high quality echocardiography procedures for transthoracic, stress and transesophageal echocardiography. Its Board of Directors is made up of representatives from the American Society of Echocardiography, American College of Cardiology, Society of Pediatric Echocardiography and the Society of Diagnostic Medical Sonography. The ICAEL has been in operation since 1996 and currently has accredited over 900 echocardiography laboratories in the United States and Canada. Please see the attached information on the ICAEL accreditation program.
- The Intersocietal Commission for the Accreditation of Vascular Laboratories (“ICAVL”) promotes high quality non-invasive vascular diagnostic testing in the delivery of health care by providing a peer-review process of laboratory accreditation. Its sponsoring organizations include: the Society for Vascular Surgery, the Society for Clinical Vascular Surgery, the Society for Vascular Medicine and Biology, the American College of Cardiology, the American Academy of Neurology, the American Society of Neuroimaging, the Joint Section on Cerebrovascular Surgery/American Association of Neurological Surgeons and Congress of Neurological Surgeons, the American Institute of Ultrasound in Medicine, the Society of Interventional Radiology, the Society of Radiologists in Ultrasound, the Society of Diagnostic Medical Sonography, and the Society for Vascular Ultrasound. The ICAVL has been in operation since 1991 and currently has over 1,400 accredited laboratories in the United States and Canada. Please see the attached information on the ICAVL accreditation program.
- The Joint Review Committee on Education in Diagnostic Medical Sonography (“JRC-DMS”) is the only nationally recognized accreditor of diagnostic medical sonography programs. The primary purpose of the JRC-DMS is to establish, maintain, and promote appropriate standards of quality (the “Standards”) for educational programs in diagnostic medical sonography and to provide recognition for educational programs which meet or exceed the Standards. These Standards are endorsed by the JRC-DMS’ nine sponsoring organizations, which include: the American College of Cardiology, American College of Obstetricians and Gynecologists, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of

Radiologic Technologists, Society of Diagnostic Medical Sonography and the Society for Vascular Ultrasound. Founded in 1979, JRC-DMS has a 25-year history recommending programmatic accreditation for over 100 programs.

- The Society of Diagnostic Medical Sonography (“SDMS”) is the largest professional sonography organization in the country, including 15,000 sonographer and physician members. SDMS promotes the delivery of high quality echocardiography, obstetrical and abdominal ultrasound, and vascular ultrasound services.
- The Society of Interventional Radiology (“SIR”) is a nonprofit, national scientific organization of physicians and allied health professionals deeply committed to improving health and the quality of life through the practice of vascular and interventional radiology. The Society promotes education, research, and communication while providing strong leadership in the development of health care policy.
- The Society for Vascular Surgery (“SVS”) is the oldest and largest national association of Vascular Surgeons in the United States. SVS members pioneered the application of non-invasive ultrasound techniques to the diagnosis of vascular disease in the 1960s and have spearheaded the development and refinement of modern protocols and procedures for accurate vascular ultrasound testing. SVS members serve on the Boards of major vascular sonographer associations as well as the major ultrasound credentialing and accrediting organizations. The SVS has worked collaboratively with these groups to advance the safety, accuracy and the quality of vascular diagnostic ultrasound for over twenty-five years.
- The Society for Vascular Ultrasound (“SVU”) is the only national professional organization dedicated exclusively to the advancement of non-invasive vascular technology used for diagnostic purposes. SVU has a diverse membership of vascular ultrasound professionals that includes vascular surgeons, vascular technologists, vascular nurses, sonographers, echocardiographers, vascular lab managers and other health care professionals. Of SVU’s 3,500 members, more than 800 are physicians.

Exhibit 1

Alabama: BLUE CROSS BLUE SHIELD OF ALABAMA

"The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. All noninvasive vascular diagnostic studies must be performed by, or under the direct supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology. Examples of appropriate certification include the Registered Vascular Technologist (RVT) credential and the Registered Cardiovascular Technologist (RCVT) credential in Vascular Technology. Direct supervision requires the credentialed individuals physical presence in the facility."

Arkansas: ARKANSAS MEDICARE SERVICES

"Noninvasive vascular studies utilize ultrasonic Doppler and physiologic principles to assess irregularities in blood flow in arterial and venous systems. The display may be a two dimensional image with spectral analysis and color flow or a plethysmographic recording.¹ A hard copy, or a soft copy convertible to a hard copy, provides a permanent record of the study performed and must be of a quality that meets accepted standards². Contrast arteriography and phlebography are standard diagnostic techniques for evaluation of arterial and venous diseases. These techniques are invasive and involve additional expense, time, discomfort and risks to the patient. Reliable, valid and accurate noninvasive studies are necessary to offset this problem. It is the responsibility of the provider to ensure the quality of the noninvasive studies. The accuracy of noninvasive vascular studies depends on the knowledge, skill and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. All noninvasive vascular diagnostic studies must be either (1) performed by, or under the general supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in Vascular Technology, and appropriate laboratory accreditation include the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), or the American College of Radiology (ACR). Effective January 1, 2005, documentation of either the RVS, RVT or facility accreditation will be required each January prior to billing electronically for that new year and with any and all submitted paper claims. Supervisory levels of diagnostic tests must be in accordance with Program Memorandum B-01-28."

Delaware, District of Columbia, Maryland, Texas, Virginia:
TRAILBLAZER HEALTH ENTERPRISES, LLC

By February 4, 2000**, all non-invasive vascular diagnostic studies, when performed by a technologist, must be performed by a technologist who has demonstrated competency in ultrasound by receiving one of the following credentials in vascular ultrasound technology:

Registered Vascular Specialist (RVS); or,
Registered Vascular Technologist (RVT).

The RVS and RVT credentials are provided by the following nationally recognized organizations*:

RVT by The American Registry of Diagnostic Medical Sonographers (ARDMS); and,
RVS by Cardiovascular Credentialing International (CCI).

Alternately, by February 4, 2000**, such studies must be performed in a facility or vascular laboratory accredited by one of the following nationally recognized accreditation organizations*. If a vascular laboratory or facility is accredited, the technologists performing non-invasive cerebrovascular arterial studies in that laboratory are considered to have demonstrated competency in cerebrovascular ultrasound:

American College of Radiology (ACR) Vascular Ultrasound Accreditation Program; and,
Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL).

Idaho: CIGNA MEDICARE

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and the physician performing the interpretation of the study. Consequently, technologists and physicians must be able to show documentation of training and experience as well as maintain these credentials at each office site. All noninvasive vascular diagnostic studies must be: (1) performed by a qualified physician, (2) performed by or under the supervision of persons that have demonstrated minimum entry level competency as evidenced by being credentialed in vascular technology, or (3) performed in facilities with laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in vascular technology. Appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) and/or the American College of Radiology (ACR). This accreditation will be required as of January 1, 2004.”

Kansas/Western Missouri, Nebraska: BLUE CROSS BLUE SHIELD OF KANSAS

"The accuracy of non-invasive diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. Furthermore, effective 12:01 A.M. July 1, 1998, all non-invasive vascular diagnostic studies must be performed by, or under the direct supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology. Examples of appropriate certification include the Registered Vascular Technologist (RVT). Supervision requires the credentialed individual's physical presence in the facility.

Appendix A

Certification for Vascular Laboratories/Vascular Technologists

In January 1996, the first revision to the local medical review policy regarding "Non-Invasive Vascular Studies" was published and included information regarding certification for vascular laboratories and vascular technicians. This article is intended to provide clarifications and guidance in relation to certification requirements.

One or more technologists in each vascular laboratory must be certified by a credentialing board recognized by the Intersocietal Commission for Accreditation of Vascular Laboratories (ICAVL) or the National Council for Certifying Agencies.

Laboratories may be certified by the Intersocietal Commission for the Accreditation of Vascular Laboratories. Certification of the laboratory itself supersedes the requirement for certification of individual technologists.

If a certified technologist supervises technologists who are not certified, the certified RVT must:

- a) be physically present during the testing; and
- b) sign the record of the test and attest to the quality of the examination.

These requirements will be necessary to payment of services provided beginning 12:01 A.M. July 1, 1998."

Louisiana: BCBS OF ARKANSAS - LOUISIANA TERRITORY

“Noninvasive vascular studies utilize ultrasonic Doppler and physiologic principles to assess irregularities in blood flow in arterial and venous systems. The display may be a two dimensional image with spectral analysis and color flow or a plethysmographic recording.¹ A hard copy, or a soft copy convertible to a hard copy, provides a permanent record of the study performed and must be of a quality that meets accepted standards². Contrast arteriography and phlebography are standard diagnostic techniques for evaluation of arterial and venous diseases. These techniques are invasive and involve additional expense, time, discomfort and risks to the patient. Reliable, valid and accurate noninvasive studies are necessary to offset this problem. It is the responsibility of the provider to ensure the quality of the noninvasive studies. The accuracy of noninvasive vascular studies depends on the knowledge, skill and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. All noninvasive vascular diagnostic studies must be either (1) performed by, or under the general supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in Vascular Technology, and appropriate laboratory accreditation include the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), or the American College of Radiology (ACR). Effective January 1, 2005, documentation of either the RVS, RVT or facility accreditation will be required each January prior to billing electronically for that new year and with any and all submitted paper claims. Supervisory levels of diagnostic tests must be in accordance with Program Memorandum B-01-28.”

Mississippi: CAHABA GOVERNMENT BENEFIT ADMINISTRATORS

“Vascular studies include patient care required to perform the studies, supervision of the studies, and interpretation of study results with copies per patient records of hard copy output or imaging when provided. The use of a simple hand-held or other Doppler device that does not produce hard copy output, or that does not permit analysis of bi-directional vascular flow, is considered part of the physical examination of the vascular system and is not separately reimbursable. That accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skills, and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. Further, effective January 1, 1998, noninvasive vascular diagnostic studies in Mississippi must be either (1) performed by persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, (2) performed by or under the direct supervision of a physician, or (3) performed in facilities with laboratories accredited in vascular technology. Direct supervision in the office setting means the physicians must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Other Comments: Due to a request from the MS Radiological Society, the effective date for implementation of required certification for technologist will be delayed until July 1, 1998.”

Missouri: MISSOURI MEDICARE SERVICES

“Noninvasive vascular studies utilize ultrasonic Doppler and physiologic principles to assess irregularities in blood flow in arterial and venous systems. The display may be a two dimensional image with spectral analysis and color flow or a plethysmographic recording. 1 A hard copy, or a soft copy convertible to a hard copy, provides a permanent record of the study performed and must be of a quality that meets accepted standards. 2. Contrast arteriography and phlebography are standard diagnostic techniques for evaluation of arterial and venous diseases. These techniques are invasive and involve additional expense, time, discomfort and risks to the patient. Reliable, valid and accurate noninvasive studies are necessary to offset this problem. It is the responsibility of the provider to ensure the quality of the noninvasive studies. The accuracy of noninvasive vascular studies depends on the knowledge, skill and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. All noninvasive vascular diagnostic studies must be either (1) performed by, or under the general supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in Vascular Technology, and appropriate laboratory accreditation include the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), or the American College of Radiology (ACR). Effective January 1, 2005, documentation of either the RVT or facility accreditation will be required each January prior to billing electronically for that new year and with any and all submitted paper claims. Supervisory levels of diagnostic tests must be in accordance with Program Memorandum B-01-28.16.”

New Jersey: EMPIRE MEDICARE SERVICES

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and physician performing and interpreting the study. Consequently, the physician performing and/or interpreting the study must be capable of demonstrating documented training and experience and maintain documentation for postpayment audit. A vascular diagnostic study may be personally performed by a physician or a technologist. Effective January 1, 1999, all noninvasive vascular diagnostic studies performed by a technologist must be performed by, or under the direct supervision of, a technologist who has demonstrated competency by being credentialed in vascular technology, or, such studies must be performed in a facility accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) or the Non-Invasive Vascular Ultrasound Accreditation of the American College of Radiology. Examples of appropriate certification include the Registered Vascular Technologist (RVT) credential and the Registered Cardiovascular Technologist (RCVT) credential in Vascular Technology. Direct supervision requires the credentialed individuals’ presence in the facility and immediate availability to the technologist performing the study.”

New Mexico, Oklahoma: OKLAHOMA/NEW MEXICO MEDICARE SERVICES

“Noninvasive vascular studies utilize ultrasonic Doppler and physiologic principles to assess irregularities in blood flow in arterial and venous systems. The display may be a two dimensional image with spectral analysis and color flow or a plethysmographic recording.¹ A hard copy, or a soft copy convertible to a hard copy, provides a permanent record of the study performed and must be of a quality that meets accepted standards². Contrast arteriography and phlebography are standard diagnostic techniques for evaluation of arterial and venous diseases. These techniques are invasive and involve additional expense, time, discomfort and risks to the patient. Reliable, valid and accurate noninvasive studies are necessary to offset this problem. It is the responsibility of the provider to ensure the quality of the noninvasive studies. The accuracy of noninvasive vascular studies depends on the knowledge, skill and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. All noninvasive vascular diagnostic studies must be either (1) performed by, or under the general supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in Vascular Technology, and appropriate laboratory accreditation include the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), or the American College of Radiology (ACR). Effective January 1, 2005, documentation of either the RVS, RVT or facility accreditation will be required each January prior to billing electronically for that new year and with any and all submitted paper claims. Supervisory levels of diagnostic tests must be in accordance with Program Memorandum B-01-28.”

New York (Upstate): HEALTHNOW, NY, INC.

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit.

Effective January 1, 1999, all noninvasive vascular diagnostic studies must be performed under at least one of the following settings: (1) performed by a physician who is competent in diagnostic vascular studies or under the general supervision of physicians who have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed by a technician who is certified in vascular technology, or (3) performed in facilities with laboratories accredited in vascular technology.

Examples of appropriate personnel certification include, but are not limited to, the Registered Vascular Technologist (RCT), the Registered Cardiovascular Technologist (RCVT), and the American Registry of Radiology Technologists (ARRT) credentials in vascular technology. Appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL).”

New York (Other): EMPIRE MEDICARE SERVICES

“The accuracy of non-invasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. Effective January 1, 1999, all non-invasive vascular diagnostic studies must be either: (1) performed by or under the general supervision of persons who have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in facilities with laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RCT) credential and the Registered Cardiovascular Technologist (RCVT) credential in vascular technology. Appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL).”

North Carolina: CIGNA HEALTHCARE MEDICARE ADMINISTRATION

“Noninvasive vascular studies include performance of the studies, supervision of the studies, and interpretation of study results with copies for patient records. The use of a simple hand-held or other Doppler device that does not produce hard copy output and that does not permit analysis of bi-directional vascular flow, is considered part of the physical examination of the vascular system and is not reported separately to Medicare for reimbursement. Reporting of the procedure includes the interpretation and some evidence of the technical component of the procedure.

The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and the physician performing the interpretation of the study. Consequently, technologists and physicians must be able to show documentation of training and experience as well as maintain these credentials at each office site.

All noninvasive vascular diagnostic studies must be: (1) performed by a qualified physician, (2) performed by or under the supervision of persons that have demonstrated minimum entry level competency as evidenced by being credentialed in vascular technology, or (3) performed in facilities with laboratories accredited in vascular technology. Examples of appropriate personnel

certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in vascular technology. Appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) and/or the American College of Radiology (ACR). This accreditation will be required as of January 1, 2002.”

Ohio: PALMETTO GBA

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter (physician). Consequently, the providers must be capable of demonstrating documented training and experience and maintain documentation for post-payment review purposes. Furthermore, all noninvasive vascular diagnostic studies must be either (1) performed by, or under the direct supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in facilities with laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Cardiovascular Technologist (RCVT) credential in Vascular Technology. If the technologist passes only the vascular technology sections, and not the physics portion of the exam, the technologist will have an additional 12 months to successfully earn the RVT and RCVT certification. Other entities that provide vascular certification should meet RVT standards.

Direct supervision requires the credentialed individuals physical presence in the facility during the examination. Appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) and the American College of Radiology. All credentialed laboratories extending their noninvasive vascular testing to include additional CPT codes have 12 months to become accredited for the new CPT codes. It is expected that all labs, after receiving accreditation, maintain an RVT or RCVT on staff to perform and supervise these procedures. Laboratory accreditation should be specific to the testing being performed.”

Pennsylvania: HGS ADMINISTRATORS

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and physician performing and interpreting the study. Consequently, the physician performing and/or interpreting the study must be capable of demonstrating documented training and experience and maintain documentation for postpayment audit. A vascular diagnostic study may be personally performed by a physician or a technologist. Effective January 1, 1999, all noninvasive vascular diagnostic studies performed by a technologist must be performed by, or under the direct supervision of, a technologist who has demonstrated competency by being credentialed in vascular technology, or, such studies must be performed in a facility accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) or the Non-Invasive Vascular Ultrasound Accreditation of the American College of Radiology. Examples of appropriate certification include the Registered Vascular Technologist (RVT) credential and the Registered Cardiovascular Technologist (RCVT) credential in Vascular Technology. Direct supervision requires the credentialed individuals' presence in the facility and immediate availability to the technologist performing the study.”

South Carolina, West Virginia: PALMETTO GBA

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. Furthermore, effective January 1, 1999, all noninvasive vascular diagnostic studies must be either (1) performed by, or under the direct supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or (2) performed in facilities with laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Cardiovascular Technologist (RCVT) credential in Vascular Technology, and appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL). Direct supervision requires the credentialed individuals physical presence in the facility during the examination.”

Tennessee: CIGNA MEDICARE

“The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and the physician performing the interpretation of the study. Consequently, technologists and physicians must be able to show documentation of training and experience as well as maintain these credentials at each office site. All noninvasive vascular diagnostic studies must be: (1) performed by a qualified physician, (2) performed by or under the supervision of persons that have demonstrated minimum entry level competency as evidenced by being credentialed in vascular technology, or (3) performed in facilities with laboratories accredited in vascular technology. Examples of appropriate personnel certification include the Registered Vascular Technologist (RVT) credential and the Registered Vascular Specialist (RVS) credential in vascular technology. Appropriate laboratory accreditation includes the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) and/or the American College of Radiology (ACR). This accreditation will be required as of January 1, 2004.”

Recommendations

Alaska, Arizona, Colorado, Hawaii, Nevada, Iowa, North Dakota, Oregon, South Dakota, Washington and Wyoming: NORIDIAN MUTUAL INSURANCE COMPANY

"The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skills and experience of the technologist and physician performing and interpreting the studies. It is recommended that noninvasive vascular studies either be rendered in a physician's office by/or under the direct supervision of persons credentialed in the specific type of procedure being performed or performed in laboratories accredited in the specific type of evaluation."
Effective for dates of service on/after 05/04.

Illinois, Michigan, Minnesota, Wisconsin: WISCONSIN PHYSICIANS SERVICE (WPS)

"The accuracy of examinations depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the providers of NIVT studies should be capable of demonstrating and maintaining documented training and experience. We recommend but do not mandate the following:

All noninvasive vascular diagnostic studies should either be

- (1) performed by, or under the direct supervision of, persons that have demonstrated minimum entry level competency by being credentialed in vascular technology, or
- (2) performed in laboratories accredited in vascular technology.

Examples of appropriate personnel certification include the following credentials:

- Registered Vascular Technologist (RVT)
- Registered Vascular Specialist (RCS)
- Registered Diagnostic Medical Sonographer (RDMS)

Examples of appropriate laboratory accreditation includes:

- Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL)
- American College of Radiology (ACR)
- The American Institute of Ultrasound in Medicine (AIUM).

Exhibit 2

42 C.F.R. § 410.33 -- Independent diagnostic testing facility.

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after July 1, 1998, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(l)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. This level of supervision is that required for general supervision set forth in § 410.32(b)(3)(i).

(2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

(c) *Nonphysician personnel.* Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(d) *Ordering of tests.* All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. (Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).) The order must specify the diagnosis or other basis for [*59100] the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF's supervising physician is in fact the beneficiary's treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.

(e) *Multi-State entities.* An IDTF that operates across State boundaries must maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it is furnishing services.

(f) *Applicability of State law.* An IDTF must comply with the applicable laws of any State in which it operates.

ATTACHMENT 1- MODEL ECHOCARDIOGRAPHY POLICY

American Society of Echocardiography Model Local Medical Review Policy for Echocardiography

12-03-2003

The accuracy of an echocardiographic study depends on the knowledge, skill, and experience of both the individual performing and recording the study (technical component) and the physician reviewing and interpreting the study (professional component). Consequently, the following requirements shall become effective *[two years from the date of the notice.]*

Requirements relating to Performance of an Echocardiographic Study

The following requirement must be met in order for the technical component of an echocardiographic study to be considered reasonable and necessary for the purposes of the Medicare Act.

An echocardiographic study must be performed (a) in a laboratory that is accredited in echocardiography; or (b) in a manner that meets both of the following requirements:

- (i) The echocardiographic study is performed by a qualified physician or by a cardiac sonographer who has been certified by an appropriate national credentialing body; and
- (ii) The study is performed in a laboratory or other setting that has designated a qualified Physician Director and a qualified Technical Director. When a qualified physician performs the study, that physician may serve the functions of both the Physician Director and the Technical Director.

For the purposes of this requirement, a Qualified Physician Director shall mean a physician who is responsible for the ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform study, and the qualification of nonphysician personnel who use the equipment. The Physician Director must evidence proficiency in the performance and interpretation of echocardiographic studies, which may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area.

The term qualified Technical Director shall mean a physician who is proficient in the performance of echocardiograms or a cardiac sonographer who has been certified by an appropriate national credentialing body.

Requirements relating to the Interpretation of an Echocardiographic Study

The following requirement must be met in order for the professional component of an echocardiographic study to be considered reasonable and necessary for the purposes of the Medicare Act.

ATTACHMENT 1- MODEL ECHOCARDIOGRAPHY POLICY

A physician who interprets an echocardiographic study must be able to show documentation of adequate training and experience and must maintain these credentials on file and available for post payment review.

ATTACHMENT 2- CQU MODEL VASCULAR POLICY

The accuracy of noninvasive vascular diagnostic studies (both physiologic and Duplex scans) depends on the knowledge, skill, and experience of the technologist or sonographer, the interpreter (physician), 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.

Accordingly, effective in four years in rural areas (meaning Metropolitan Statistical Areas of less than 50,000 inhabitants as determined by the last census) and effective in three years in all other areas, all noninvasive vascular diagnostic studies must meet one of the two following standards: (1) the services are performed in facilities with laboratories accredited by an appropriate national accreditation body, such as [Medicare carrier to insert the acceptable options] and/or (2) 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, such as [Medicare carrier to select bodies]. The technologist or sonographer must successfully pass all required examinations by the recognized credentialing organizations. This policy has no application to physicians who provide the technical component of non-invasive vascular studies.