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# Medicare

## **Comments and Responses Regarding Draft Local Coverage Determination: Transthoracic Echocardiography (TTE)**

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Transthoracic Echocardiography (TTE) LCD. The official notice period for the final LCD begins on April 15, 2009, and the final determination will become effective on July 1, 2009.

### **Comment:**

A commenter noted that the coding instructions in the TTE supplemental article says hospitals should not code the contrast media (Q9955, Q9956, Q9957) in addition to the C codes. This is incorrect. The C Code describes the procedure done and the Q code describes the contrast used. It is an "N" status and CMS instructs us to report "N" status codes to accurately calculate the APC payment to which the supply code is bundled. This contrast is often expensive and other payers pay these codes. We should be billing both codes together.

Two examples were cited from other contractors.

### **Response:**

We appreciate the commenter having identified this error in our coding instructions. We apologize for the confusion will revise the article accordingly.

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### **Comment (ASE):**

The American Society of Echocardiography submitted a multipage document with many comments and a list of ICD-9 codes. Many providers submitted almost identical comments in part.

Under the draft LCD, an echocardiogram ordered for a high risk patient is considered screening, regardless of the results of the study. Under current Medicare guidelines, it is generally allowable to

use a diagnostic code that appropriately reflects the results of a study, regardless of why the study was initially ordered.

**Response:**

We respectfully disagree with the commenters' interpretation of screening tests. A screening test is one that is performed without signs or symptoms of disease. With the specific exceptions noted in Title XVIII, screening services are not covered or reimbursable under Medicare (see Social Security Act Title XVIII Section 1862(a)(7)). While the test may be diagnosis-coded based on the results, it does not change the reason why the test was performed which is the basis for the coverage.

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**Comment (ASE):**

The draft LCD would preclude Medicare coverage of Doppler unless specifically ordered for a particular indication. The draft LCD includes the following statement:

*Typically, Doppler is indicated in the evaluation of some heart murmurs, valvular problems, suspected congenital heart disease, complications of myocardial infarction, or cardiomyopathy. When performed routinely with all echocardiographic exams (i.e., without a clinical indication), the service is not covered by Medicare. This is true even when the results of the test reveal abnormalities. When the test is performed without a specific indication, it is considered routine screening, and must be billed with a screening ICD-9-CM code to indicate the reason for the test. (Emphasis added.)*

ASE strenuously objects to this provision of the Draft TTE LCD. In fact, both spectral and color flow Doppler are commonly considered crucial components of a comprehensive echocardiogram, and both the Doppler and imaging components of echocardiograms are commonly considered critical in order to accurately diagnose a broad range of cardiovascular conditions. It is for this reason that Medicare claims data indicates that Doppler studies are performed in conjunction with over 90% of TTEs. In our experience, common co-morbid conditions often are detected for the first time during an echocardiogram. A few very common examples include patients with coronary artery disease who also have previously undiagnosed mitral or aortic valve disease; hypertensive patients with aortic root disease; and previously undiagnosed aortic regurgitations; and older patients with heart failure symptoms that are found to have normal LV ejection fraction, but LV diastolic dysfunction or pulmonary hypertension on the Doppler component of the exam.

It is relatively rare to encounter clinical circumstances under which only the imaging component of a transthoracic echocardiogram is appropriate. It is true that color/spectral Doppler may not be useful or appropriate in certain relatively small and well-defined patient populations when there is a recent comprehensive examination and the test is being ordered for re-evaluation of a limited problem. An example is pericardial tamponade: An initial 2D and Doppler exam is needed to detect this potentially lethal condition. If tamponade is diagnosed and treated with surgery or percutaneous drainage, subsequent limited exam(s) are needed to assess re-accumulation of fluid prior to drain removal, but generally Doppler is not required. By contrast, if the physician elects to follow a significant pericardial effusion, then follow up 2D and Doppler exams are needed at the discretion of the physician, based on

the condition of the patient and the reason for the pericardial effusion (post-surgical; post percutaneous intervention or idiopathic). The LCD draft as written does not lend itself to such common, everyday conditions –conditions that frequently face the practitioner and patients.

This reflects a substantial change in policy, and is inconsistent with the CMS' rationale for “bundling” Doppler studies into TTE, a change adopted precisely because spectral and color Doppler are now considered integral to virtually all TTE studies.

### **Response:**

The use of Doppler provides information that is used to identify abnormal flow characteristics related to native and prosthetic valve function and dysfunction, shunts, congenital defects, pulmonary vascular disease and cardiac hemodynamics. We agree with the commenters that Doppler has become an essential and major part of cardiac ultrasound, and for which there does exist many indications. This LCD does not preclude the use of Doppler when ultrasonically examining the heart, but specifically includes it, indicating that it is covered when there is a *clinical indication*. Some commenters have made a point that the new CPT codes even bundle the Doppler into a single code with the transthoracic study (CPT 93306). We also note that CPT has retained the transthoracic test without the Doppler and color-flow components which may not always be needed or performed. NGS claims history indicates a very high concordance for performance of the echocardiogram and these add-on codes, which all are generally reimbursed. We agree that there is a very frequent indication for Doppler and color flow to accompany the transthoracic study, and do not envisage that there will be a significant change in this pattern of use based on this LCD. We believe that in those instances in which it is considered integral to the study, based on the anticipated information being sought, Doppler and color-flow would be judged to be medically necessary.

Nonetheless, we agree with the ASE that the purpose of the echocardiogram is to examine the heart so as to determine a complete evaluation of its anatomy and function, recognizing that it may not be possible to dissociate the multiple structures and pathophysiologic responses from the function of these structures and the overall function of the entire organ and patient.

We will revise the LCD to clarify that the use of the Doppler is inherent in the ultrasonic cardiac evaluation. However, if the test reports fail to document the use of this technique to assess these structures and function (e.g., measurement of valvular insufficiency or stenosis, myocardial diastolic function, etc as described by the ASE), or if the medical records fail to document that the examination was “clinically necessary” as ASE has indicated (e.g., follow-up of pericardial effusion size) then the Doppler portion of the test may be considered medically unnecessary and denied.

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### **Comment (ASE):**

The draft LCD indicates that routine (yearly) re-examination for a host of relatively common cardiac conditions are not covered. While the draft is generally consistent with the ACC/ASE Appropriateness Guidelines in this regard, the Appropriateness Guidelines indicate that re-examination is appropriate if

there is a change in clinical circumstances, and it is unclear how the draft LCD would accommodate this. In the absence of NEW symptoms or NEW clinical findings, another echo within the year would not be appropriate. However, the same patient with new symptoms or clinical findings suggesting progression of mitral valve disease or other cardiac dysfunction should have a new exam based on these new clinical findings, even though the echo was previously performed. We recommend that the LCD differentiate between a re-examination of a particular previously detected condition versus a NEW examination for a NEW or CHANGING clinical signs or symptoms.

Even more importantly, the draft LCD does not address the crucial question of how a physician (or a hospital or other provider) is to know whether or not a study was conducted within the prior year, since patients are often unreliable sources of this type of information. Moreover, the application of these rules to patients in Emergency Room settings is especially problematic, since, in these cases it is entirely inappropriate for coverage to be denied based on prior testing, the results of which may not be available to the Emergency Room physician or others treating the patient under emergency circumstances.

### **Response:**

We appreciate the commenters' recognition that the draft is consistent with the ACC/ASE Appropriateness Guidelines in identifying those conditions for which repeat examination is and is not indicated. We agree with this commenter that *"re-examination is appropriate if there is a change in clinical circumstances."* The utilization guidelines section of the LCD specifically states *"Repeat studies are appropriate to monitor changes in cardiac structure or function when there are clinical changes in the status of the patient, or when disease progression is otherwise suspected."* Furthermore many of the individual indications also note that the frequency of re-examination may be related to changes in the patient's status or clinical symptoms.

We agree that the tracking of previous tests by a patient or obtaining copies of records by other providers may be problematic. However, it is also not appropriate that the Medicare Program bear the sole burden of unnecessary repeat testing. The purpose of the Medicare Program is to provide health insurance for the beneficiary for services that are medically necessary and reasonable. This may be separate and apart from reimbursing all services provided by physicians to Medicare beneficiaries. It is not anticipated that this would be an issue in patients under the continuous care of a single physician or group, where such information and records should be readily available. Certainly in such instances the physician should be held to this standard. In those instances in which a physician has documented a good faith effort to identify previous tests performed and to request copies of them from previous providers, if repeat tests were denied, then NGS could reimburse such tests on appeal.

The ASE is correct when it suggests that the Program must consider patients in an emergency situation differently than those in non-emergent situations. We will revise the LCD to exclude Emergency Room and other emergency services from any prohibition on repeat testing. While the Emergency Room claims would be identifiable based on the place of service (23) identified on the claim, other emergency services provided at other sites would require post-pay review of the documentation provided in the medical record.

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**Comment (ASE):**

We note that, in the section addressing stress echocardiography, the Draft TTE LCD states:

*Since echocardiography, nuclear testing, magnetic resonance imaging (MRI), and positron emission tomography can yield overlapping if not identical information, often with similar or comparable accuracy, when two or more of these tests provide equivalent information, one (but not both/all) will be covered when medically necessary.*

First, this provision holds the performing physician and the facility responsible for the physician who orders multiple tests at the same time as well as multiple tests ordered by different physicians. In cases where the diagnostic tests listed above are performed in different entities, departments and by different physicians (which is common), how could this be monitored and who is responsible? In short, the ASE strongly believes that, in the absence of a reliable system of electronic records, it is impractical for payers, including the Medicare Program, to deny coverage for multiple tests.

Second, as a practical matter, this provision likely would result in increased liability for Medicare beneficiaries, who would be responsible for paying for multiple procedures.

Third, in many clinical situations, a suspected clinical abnormality is identified by one tests that is best or more clearly defined or confirmed by a complementary imaging modality. While a “shotgun” approach to imaging is not desirable, it is difficult to determine up front which modality should be ordered, since each imaging modality suffers from its own set of accuracy restraints based upon patient size and site of care and other factors.

Fourth, while there is some overlap among these tests, echocardiography may provide information that is incremental to and not available with these imaging modalities. If this policy is to be implemented, it must permit coverage for echocardiography when a new indication is provided ...

We suggest that the LCD focus on the quality requirements for appropriate imaging without denying coverage of medically necessary tests that may result from technical or other constraints of a previously ordered study involving modality. Focusing on quality should minimize as much as possible the need for complimentary imaging. (We do agree, however, that the patient’s medical record should establish the need for multiple procedures, when ordered by the same physician).

**Response:**

The ASE notes in its comments that repeat testing may occur not infrequently. However, it is also not appropriate that the Medicare Program bear the sole burden of unnecessary repeat testing. The purpose of the Medicare Program is to provide health insurance for the beneficiary for services that are medically necessary and reasonable, rather than reimbursing any and all services provided to Medicare beneficiaries. The “shotgun” approach to medicine is neither efficient nor in the best interests of the patient. The LCD specifically addresses only the issue of duplicative information from multiple tests,

and not that multiple tests are performed. Not only does unnecessary testing strain the availability of individual services and the affordability of the health care system, but it also subjects patients to the potential risks and uncertainty of false positive tests, and unnecessary complications or adverse event. It is the responsibility of the treating physicians to incorporate prior testing into the management of their patients. This does not preclude the use of multiple tests when there is anticipated medical necessity for the test; especially when specific additional data is sought, or when a completed test is inconclusive or needs confirmation in order to make a management decision. The medical record should clearly document the reasons for performing each test, as well as prior data which has been reviewed, and include documentation that specific missing test results were requested and not received, necessitating repeat or additional testing. We believe that the ASE comment “that this provision likely would result in increased liability for Medicare beneficiaries, who would be responsible for paying for multiple procedures” is self-serving as it implies that services should be complete covered/reimbursed regardless of the medical necessity of the service. NGS agrees that all reasonable and medically necessary services should be paid. Although ASE states, “While a ‘shotgun’ approach to imaging is not desirable, it is difficult to determine up front which modality should be ordered, since each imaging modality suffers from its own set of accuracy restraints based upon patient size and site of care and other factors,” we believe that clinical judgment does afford physicians the ability to identify those tests that are expected to provide the information necessary to manage patients and not to have to use a shotgun approach.

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**Comment (ASE):**

With respect to stress echo, we urge CMS to provide coverage for dobutamine stress echo for low gradient, low output [aortic stenosis] as well as dobutamine stress to detect clinically silent transplant coronary disease.

**Response:**

We agree with ASE’s request to include these indications for stress echocardiography, but note that the ICD-9 diagnosis codes are already included among those diagnoses supporting medical necessity (424.1 and 996.83).

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**Comment (ASE):**

The list of ICD-9CM diagnosis codes that we believe are appropriate for resting TTE are attached.

**Response:**

We have reviewed the list of ICD-9 codes submitted by the ASE supporting the medical necessity of resting TTE. Many of the ICD-9 codes are already listed in the LCD. Of those not already present we will add the following codes: 017.93-017.95, 279.11, 392.9, 426.50-426.6, 436, 518.7, 747.5, 747.81-747.83, 747.9, 748.0, 748.5, 750.6, 754.81-754.82, 758.0 -758.2, 758.6, 759.0, 759.7, 759.9, 780.1, 799.02, 799.1, 963.0, 972.xx, 996.63, 996.66, 999.30, 999.4, V12.53, V12.54, V58.11, V58.44, V58.69, V59.8, V67.51 and V76.51.

We will not include many of the codes described as “unspecified” as we believe that the physician should be able to clinically provide more information so that another code could be submitted: 272.4, 398.90, 416.9, 427.9, 429.2, 443.9 and 785.0.

A number of suggested ICD-9 codes are screening in nature and will not be included as requested. Some of these diagnoses reflect preoperative screening which is not a covered benefit, unless there is clinical evidence that the beneficiary has cardiac signs or symptoms, or history of cardiac disease, so that the preoperative evaluation is necessary. In these instances the underlying disease or relevant signs/symptoms should be coded. Similarly, echocardiography is considered screening, in the absence of signs or symptoms of cardiac disease, when performed because of the presence of peripheral vascular disease (e.g., peripheral artery aneurysms or dissection). Suggested ICD-9 codes not included are: 272.0, 272.4, 278.0, 435.2, 440.20, 440.4, 442.0-442.3, 442.81-442.89, 442.9, 443.0, 443.1, 443.21-443.24, 443.29, 443.81, 443.89, 443.9, 444.0-444.1, 780.03 and V72.81.

Previous versions of this LCD have grouped the diagnoses for hypertension by whether the hypertension is accompanied by heart failure. In those instances of hypertension without heart failure a limited echocardiogram would be covered, whereas a complete echocardiogram would be covered if heart failure were present. We believe that this should remain unchanged. We are in need of evidence demonstrating that echocardiography changes the long term outcomes in patients who are without signs or symptoms of heart failure or other cardiac manifestations or disease, compared to those patients clinically treated for their hypertension. For those patients with signs or symptoms suggesting failure in the absence of an established diagnosis, or for whom there are other cardiac manifestations of cardiac disease, symptom codes or codes describing these other manifestations (e.g., murmurs,) may also be coded to support the medical necessity of the complete test. Doppler studies (93320 and 93325) may be indicated in the assessment of the hypertensive patient to evaluate diastolic function.

In the absence of any literature or explanatory information, we believe that a number of the suggested diagnoses would not normally support the medical necessity of an echocardiogram: 017.90-017.92, 017.96, 276.50-276.52, 278.0, 435.2, 458.21, 780.03, 7798, 799.01, 935.1-935.2, 995.1 and V42.3.

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**Comment (ASE):**

We strongly support a number of the provisions of the Draft TTE LCD related to quality. In particular, we applaud the decision to retain the Training Requirements that were included in the LCD previously adopted by the New York carrier, which require that certain quality requirements be met by entities (including hospitals) that bill Medicare for echocardiography services. Our sole suggestion with respect to these provisions is that NGS consider eliminating the provision that would allow any physician with hospital staff privileges to obtain Medicare coverage for his or her echo interpretations. We do not believe that physicians should be entitled to bill Medicare for echo interpretations solely because he or she has obtained staff privileges to do so, since hospital staff privilege requirements vary widely within any community and may be obtained for a myriad of reasons unrelated to quality.

We also believe that it may be useful for NGS to clarify the quality requirements for stress tests.

Paragraph (7) of Section E of the Draft TTE LCD, under "Limitations" states:

Stress testing should be conducted by well trained personnel. Only technicians and physicians familiar with normal and abnormal responses during exercise are trained to recognize or prevent untoward events.

While we fully agree with this statement, to avoid confusion, it may be useful for the Draft TTE LCD to specifically state what types of qualifications are required. Again, we would advise using approved ACC/AHA/ASE training standards for physicians, accreditation by ICAEL for facilities, and certification of cardiac sonographers by recognized national credentialing organizations as the appropriate quality standards. However, since these quality requirements were not previously imposed for stress echocardiography by the New York or other area carriers, we believe that all providers should have a two year grace period to comply with these requirements.

**Response:**

We appreciate the ASE support on the quality requirements. Having staff privileges to interpret echocardiograms at a hospital that participates in the Medicare program is an outdated and insufficient sole criteria for determining quality, and will be deleted. We agree that quality requirements should encompass approved ACC/AHA/ASE training standards for physicians, accreditation by ICAEL for facilities, and certification of cardiac sonographers by recognized national credentialing organizations as the appropriate quality standards.

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**Comment:**

We support NGS' proposal to cover 3D echo. Along these lines, we would refer NGS to the ASE's recent publication on the topic of 3D echocardiography **3D Echocardiography: A Review of the Current Status and Future Directions**. <http://www.asefiles.org/3D.pdf>. We believe that 3D also should be covered for congenital lesions, planning interventions such as device closure of defects, assessing mechanical complications of myocardial infarction and endocarditis. In addition, we note that the Draft TTE LCD does not address the use of 3D echo in conjunction with stress echo, and would hope that the Draft TTE LCD will be modified to include appropriate indications for 3D with these studies. We encourage NGS to remain open to additional indications of 3D echocardiography in the future.

**Response:**

We appreciate ASE's support to cover 3D echocardiography. We agree that the quality of the imaging is more advanced than that of 2D imaging. We anticipate that these 3D studies will not replace the 2D studies currently performed but rather will represent an additional layer of testing. However, it will be necessary to establish whether these new images are changing outcomes or just represent examples of advanced technology. We have reviewed the recommended reference. It explains the technology and includes the data validating the accuracy and reduced acquisition times of the tests. It does not, however, offer outcomes data for the 3D studies compared to 2D studies. It concludes that standardized and focused 3D protocols will be developed and refined to optimize clinical application of this technique, and notes that further technological improvements and additional clinical studies will broaden the list of appropriate applications for this exciting new ultrasound modality. It is a



technology in evolution. Although it provides improved calculation of volumetric studies when compared to 2D echocardiography, we still need to see data on whether it enhances outcomes. When performed in conjunction with transthoracic studies, the application of 3D echocardiography is covered for the pre-operative planning of mitral valve repair for prolapse, and the accurate calculation of mitral valve area in patients with moderate to severe mitral stenosis. This is a rapidly evolving technology, and we anticipate multiple opportunities to expand the indications for this service in the future.

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**Comment:**

The Article indicates that CPT codes 93303 (C8921 for OPPS billing) and 93304 (C8922 for OPPS billing) are used to report transthoracic echocardiography when congenital heart disease is suspected and found. In cases where it is not found, the non-congenital codes should be reported. We believe that if clinical signs suggest a need for a congenital exam, then a congenital exam should be reported, regardless of whether congenital disease is found.

**Response:**

We believe that the additional work of performing an echocardiographic study is related to the definition and extent of a congenital defect, rather than to the initial identification of its presence. Certainly, the presence of such abnormalities in the Medicare population, in whom such defects may be suspected but have not been previously diagnosed, is small. We will respectfully decline to revise the coding instructions at this time.

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**Comment:**

One provider added to this letter that he was concerned that the LCD would result in hardships to many employees in the hospital-based laboratory with which he is associated.

**Response:**

We believe that revisions in this LCD will not create significant changes in the utilization of these tests compared to previous versions of this LCD. We are aware that the change in CPT coding, to bundle the Doppler and color-flow codes into the transthoracic code (93306), will reduce reimbursement. However, this is a CPT and Physician Fee Schedule effect and is not related to this LCD.

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**Comment:**

One commenter stated that she thought that "...these changes greatly endanger the female patients in neglecting their signs and symptoms because they do not fall under the CMS indications. We must broaden our thinking to include these high risk women who do not present the same as the male population.

**Response:**

We do not believe that this LCD preferentially favors or neglects one gender or the other. The LCD is written to identify those indications and diagnoses for which echocardiographic testing is medically necessary. Not only are many diagnoses for diseases and etiologies included, but the LCD also includes diagnosis coding specific for coding using signs and symptoms. The commenter has expressed her concern that we will "endanger female patients by neglecting their signs or symptoms." We have endeavored to include all relevant signs and symptoms related to cardiac disease, and would be very receptive to reviewing any other additional suggestions.

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**Comment:**

Another provider also stated, "I commend you for including criteria that are synonymous with quality such as ICAEL lab accreditation and National Board of Echo certification as requirements for those providing these services. It is important that contrast agent use be encouraged when images are not adequate to answer the question posed."

**Response:**

We appreciate the commenter's gracious words. The Medicare Program has as its goal not only to fund medical care to the elderly and disabled, but also that it be quality care. We believe that intent of these LCDs is not restrictive but rather to identify those indications for which these services are reimbursable and therefore available to promote the health and well-being of the Medicare population.

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**Comment:**

A commenter stated that there are many indications for the use of 3D technology and it might be a good time to get rid of some of the antiquated information in the policy.

**Response:**

We appreciate the commenter's desire to streamline this LCD, but no recommendations for specific editing were offered. We would welcome such an opportunity in the future.

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**Comment:**

The cardiology representative to the New York State Medical Society Interspecialty Committee reviewing all LCDs stated that he had several comments on this LCD. He stated that the indication section largely omits the indication for echo and evaluation of chest pain in patients without known cardiac disease in whom cardiac disease is suspected but cannot be excluded. The recommendation is that chest pain in patients without cardiac disease where cardiac disease is suspected but cannot be excluded should be a valid indication for an echo.

**Response:**

While we agree with the commenter that the diagnosis of chest pain may be an appropriate use of echocardiography, we believe that we have already included such indications in the LCD. In addition to identifying its use in evaluating patients for acute ischemic disease, we have also included ASHD, infarction, angina, mitral valve prolapse, hypertrophic and other cardiomyopathies, pericarditis, and "other" and unspecified chest pains among the diagnosis codes supporting the medical necessity of this test.

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**Comment:**

An IDTF provider asked that the LCD be clarified in relation to the training requirements for non-physician personnel in an IDTF setting. He would like the LCD to state that requirements in an IDTF are based on individual technician qualifications, and that technicians must be registered in this setting.

**Response:**

We agree with the commenter that under 42 CFR 410.33, non-physician personnel performing tests in an IDTF *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 absence of a State licensing board, the technician must be certified by an appropriate national credentialing board.* (Please see LCD# L28135, on Independent Diagnostic Testing Facilities.)

We will revise the LCD to include this requirement.

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**Comment:**

An Illinois physician commented on the restriction in the LCD for performing Doppler studies routinely with an echocardiogram. She feels that Doppler can detect abnormalities that a stethoscope will not, especially for patients in intensive care. The primary care physician needs Doppler even more, as they are less experienced in finding abnormalities.

**Response:**

We are disheartened by this commenter's suggestion that there is a need to do more testing to compensate for a lack of basic physical diagnosis skills. The purpose of a test is to answer questions posed by a provider in the care of the patient, and not to substitute for basic examination skills. Tests should be performed at specific instances when there are clinical indications for them as determined by the patient's status and condition. Nonetheless, we do believe that the indications and diagnoses supporting the medical necessity of Doppler tests in conjunction with echocardiograms is so broad that the LCD does encompass most diagnoses for which this test would be done in the interest of obtaining data and information to be used in the management of the patient and in determining outcomes.

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**Comment:**

An ultrasound technician stated that echocardiograms are a tool for many in need with heart problems whether silent or actively occurring, and may be life-saving. She further states that "...this is a specialty that only Registered Echocardiographers should be able to perform."

**Response:**

We agree that these tests may be of considerable value in diagnosing and managing patients, and also agree that quality testing is a necessity.

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