

**SUBCHAPTER II. RECOGNITION OF NATIONAL CERTIFYING ORGANIZATIONS
FOR NONINVASIVE SCREENING OF CARDIOVASCULAR DISEASE
28 TAC §21.4301**

1. INTRODUCTION. The Commissioner of Insurance adopts new Subchapter II, §21.4301, concerning the recognition of national certifying organizations for noninvasive screening of cardiovascular disease. The new section is adopted with changes to the proposed text published in the November 27, 2009 issue of the *Texas Register* (34 TexReg 8458).

2. REASONED JUSTIFICATION. This new section is necessary to implement that part of House Bill (HB) 1290, enacted by the 81st Legislature, Regular Session, which adds the Insurance Code Chapter 1376. The Insurance Code §1376.003 establishes minimum coverage requirements for screening medical procedures for the early detection of cardiovascular disease. Section 1376.003 mandates that the minimum coverage required to be provided under the section is coverage of up to \$200 for certain screening tests every five years, performed by a laboratory that is certified by a national organization recognized by the Commissioner by rule.

The intent of HB 1290 is to “[expand] access to medical screenings to increase the early detection of cardiovascular disease.” (TEXAS STATE SENATE STATE AFFAIRS COMMITTEE, BILL ANALYSIS (ENGROSSED), HB 1290, 81ST Leg., R.S. (May 18, 2009)). Under the Insurance Code §1376.003, a health benefit plan that provides coverage for screening medical procedures must provide this minimum coverage to males older than

45 years of age and younger than 76 years of age and to females older than 55 years of age and younger than 76 years of age, who: (i) are diabetic; or (ii) have a risk of developing coronary heart disease, based on a score derived using the Framingham Heart Study coronary prediction algorithm that is intermediate or higher. According to the bill analysis, “[by] requiring health plans to provide some coverage for these screenings, more individuals will benefit from early detection, possibly saving lives and reducing related long-term medical care expenses.” The Insurance Code §1376.003 mandates that covered individuals who qualify for screening services will be provided a minimum coverage of up to \$200 for noninvasive screening tests for atherosclerosis and abnormal artery structure and function using either: (i) computed tomography scanning measuring coronary artery calcification (CT screening); or (ii) ultrasonography measuring carotid intima-media thickness and plaque (IMT screening). New §21.4301 is necessary for the recognition of national certifying organizations for laboratories for purposes of the minimum coverage requirement in the Insurance Code §1376.003 as mandated by that section.

Following publication of the proposed new section in the *Texas Register* on November 27, 2009, the Department received written comments from interested parties. In response to the written comments, the Department has changed some of the proposed language in the text of the rule as adopted. None of the changes made to the proposed text materially alter issues raised in the proposal, introduce new subject matter, or affect persons other than those previously on notice. The Department has made a change to §21.4301(3) as proposed in response to comment. Section

21.4301(3) as proposed provides that the Commissioner recognizes "an organization recognized by the Centers for Medicare and Medicaid Services" pursuant to the Insurance Code §1376.003(b). Section 1376.003(b) requires the Commissioner to recognize national organizations that certify laboratories to perform the screening tests for atherosclerosis and abnormal artery function that are set forth in the Insurance Code §1376.003(b)(1) and (2). The Department has received a written comment stating that the statutory requirement concerning certified laboratories is ambiguous and contradictory because the spectrum of providers that furnish such services include physician practices, hospitals, and imaging centers. The commenter asserts that each of these provider types may be accredited by the certifying organizations included in §21.4301 as proposed. As such, the commenter opines that a reasonable interpretation of the Insurance Code §1376.003 requires minimum coverage for the designated screening tests not only when performed by a laboratory, but any time the test is performed by a person certified by a recognized certifying organization to perform the test. The Department has changed §21.4301(3) in response to this comment to clarify that the scope of the paragraph includes "a certifying organization recognized by the Centers for Medicare and Medicaid Services" among those organizations that may certify a laboratory for purposes of the Insurance Code §1376.003. Additionally, new §21.4301 retains the proposed language identifying that the certification in question applies to a laboratory. New §21.4301 as changed therefore clarifies that there are three categories of national certifying organization that the Commissioner recognizes for purposes of the Insurance Code §1376.003: (i) the American College of Radiology; (ii)

the Intersocietal Accreditation Commission; or (iii) a certifying organization recognized by the Centers for Medicare and Medicaid Services (CMS). This change clarifies that entities directly recognized by CMS to perform the designated cardiovascular screening tests are not necessarily within the scope of §21.4301. Rather, §21.4301 provides that the Commissioner recognizes those certifying organizations recognized by CMS to provide certification of laboratories for the performance of the subject screening tests. Read as a whole, §21.4301 as changed clarifies that the Commissioner recognizes organizations in the capacity of laboratory certification to perform the CT and IMT screening tests rather than in any other capacity. This interpretation reflects the statutory minimum coverage requirement concerning cardiovascular screening tests performed by a laboratory as provided in the Insurance Code §1376.003 without expanding the requirement in a manner not specified in the statute.

3. HOW THE SECTION WILL FUNCTION. New §21.4301 recognizes the following organizations for the purpose of providing certification for laboratories that perform screening tests for atherosclerosis and abnormal artery structure and function in accordance with the Insurance Code §1376.003: (i) the American College of Radiology; (ii) the Intersocietal Accreditation Commission; or (iii) a certifying organization recognized by the Centers for Medicare and Medicaid Services.

4. SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Expansion/revision of provider credentialing.

Comment: A commenter states that HB 1290 is intended to provide coverage for early detection of hidden cardiovascular disease in the at-risk yet asymptomatic population; i.e., healthy-looking individuals with two or more cardiovascular risk factors. The commenter states that such individuals are found only at the primary care level and rarely appear at secondary or tertiary care facilities such as hospitals or advanced cardiovascular centers. The commenter opines that, in order to reach the target population, the recognition of a certifying organization should not effectively prohibit testing performed at primary care practices. To address this concern, the commenter recommends adoption of existing CMS standards concerning noninvasive vascular testing. The commenter accordingly offers guidance issued by the Texas Medicare Administrative Contractor in *Limited Coverage Determination L26744* to suggest that:

- (i) physicians performing and/or interpreting the non-invasive vascular diagnostic studies be required to demonstrate documented training through recent residency training or post-graduate Continuing Medical Education (CME) and experience and to maintain that documentation for post-payment review; and
- (ii) technologists performing the non-invasive vascular diagnostic studies must demonstrate competency via a credential in vascular ultrasound technology. Such credentials would include: (i) Registered Vascular Specialist, provided by Cardiovascular Credentialing International; (ii) Registered Vascular Technologist, provided by the American Registry of Diagnostic Medical Sonographers; or (iii) Vascular Sonographer, provided by the American Registry of Radiologic Technologists, Sonography.

The commenter additionally recommends inclusion of another standard from the Texas Medicare Administrative

Contractor guidance, such that the studies may be performed in a facility or vascular laboratory accredited by the American College of Radiology (ACR) Vascular Ultrasound Accreditation Program or the Intersocietal Commission for the Accreditation of Vascular Laboratories. The commenter states that such a standard would be consistent with current insurance industry standards and the intent of the legislation while simultaneously satisfying concerns regarding the qualifications of providers. Another commenter states that recognition of only the national certifying organizations proposed by the Department will result in the provision of access to cardiovascular risk stratification only through the provision of calcium scoring. The commenter indicates that calcium scoring tests deliver an amount of radiation that is not justified for a screening indication and increase the risk for radiation-induced cancer for patients that receive repeated coronary artery calcium CT scans. The commenter states that ultrasound imaging, in contrast, does not use ionizing radiation or require contrast and has been demonstrated to be safe over decades of use. The commenter further states that the Intersocietal Accreditation Commission (IAC) is considering development of a program for the carotid intima-media thickness (IMT) measurement that would accept applications for accreditation in late summer 2010 and that would involve 12 - 16 weeks for processing of the applications. The commenter also notes that the proposed IAC standard will, according to the IAC, require competence in the performance of duplex scanning in the extracranial system. The commenter asserts that Doppler spectral analysis: (i) is not needed for IMT testing; (ii) is much more technically demanding than the imaging required for carotid IMT testing; and (iii) will result in establishing an

unreasonable standard that will limit the number of potential providers to a population not likely to be involved in cardiovascular prevention. As to the current accreditation program for complex arterial testing, the commenter asserts that there are approximately 90 accredited vascular facilities in Texas, primarily concentrated in large cities and including vascular surgery and radiology practices. The commenter asserts that neither of these practice types are appropriate candidates for risk stratification screening because: (i) vascular surgery practices manage patients who have known or suspected cardiovascular disease; and (ii) radiology practices do not manage patients but instead receive referrals for specific imaging services. By contrast, the commenter opines that a primary care physician is better positioned to integrate test results into overall healthcare planning for individual patients and to tailor such planning on an individual basis. For these reasons, the commenter recommends adoption of the following rule text: *“With respect to ultrasonography measuring carotid intima-media thickness and plaque, a health benefit plan shall not deny coverage for a screening test described in §21.4301 of this subchapter (relating to Applicability), [sic] provided that the test is performed by a person or laboratory who meets one of the following standards. The test may be performed by a non-physician provider who is certified in ultrasonography by an organization recognized by the Centers for Medicare and Medicaid Services, such as the American Registry for Diagnostic Medical Sonographers (ARDMS) or Cardiovascular Credentialing International (CCI) or, upon such time as a laboratory accreditation program for carotid intima media [sic] thickness testing has been established by one of the following organizations: [i] The American College of*

Radiology; [ii] The Intersocietal Accreditation Commission [IAC]; [iii] An organization recognized by the Centers for Medicare and Medicaid Services; or [iv] Another organization that the Commission may recognize at some future time. Additionally, the carotid IMT test can be performed personally by a board-certified physician, who can demonstrate training in the performance of ultrasonography measuring carotid intima-media thickness testing.” The commenter asserts that this suggested language is consistent with HB 1290 in that it allows for certified providers to be "deemed" by health plan issuers. The commenter states that the suggested language also allows for issuer discretion to negotiate with physician providers on the subject of demonstrated training prior to identifying qualified providers. The commenter argues that the legislative language is ambiguous and contradictory in requiring “certified laboratories” to provide the screening services indicated in §1376.003 because the spectrum of providers that furnish such services include physician practices, hospitals, and imaging centers. The commenter asserts that each of these provider types may be accredited by the certifying organizations included in §21.4301 as proposed. The commenter, therefore, opines that a reasonable interpretation of the Insurance Code §1376.003 requires minimum coverage for the designated screening tests not only when performed by a laboratory, but when performed by a person certified to perform the test. The commenter further argues that recognition of individual certifications would be consistent with the introduction of the proposal, which referred to “recognition of provider credentials.” A third commenter opines that neither the IAC nor the ACR provides a program for providers of IMT testing at this time and states that, should one

be developed, the commenter does not believe the program will be an appropriate verification of provider competence. The commenter asserts that: (i) such programs historically address facility accreditation rather than certification of individuals; and (ii) such accreditation requirements are generally more extensive and involve coordination of various individual activities within the institution. The commenter states that such requirements are not necessary to determine physician competency. As such, the commenter requests that the Department reconsider its proposed approach to validating the competence of providers.

Agency Response: The Department disagrees with the suggested changes. The Insurance Code §1376.003(b) requires the Commissioner to recognize a national certifying organization for laboratories for purposes of minimum coverage requirements under §1376.003. Specifically, §1376.003 specifies that the minimum coverage required to be provided under the section is coverage of up to \$200 for designated noninvasive screening tests “performed by a laboratory that is certified by a national organization recognized by the commissioner by rule...” HB 1290 does not address recognition of certifying organizations or other standards for specific application to individual physicians and technologists, and the existence of individual certification programs does not alter the plain language of the statute. The Department further disagrees that recognition of national certifying organizations for laboratories effectively prohibits testing outside of the certified laboratory setting. A health benefit plan that provides coverage for noninvasive screening tests for atherosclerosis and abnormal artery structure and function is not prohibited under HB 1290 from continuing such

coverage, including coverage of testing performed at primary care facilities. HB 1290 does not diminish the extent of screening coverage obligations under health benefit plans. Instead, it creates a minimum standard for coverage that a health benefit plan is required to provide. In response to comment that recognition of "certified laboratories" creates an ambiguity given the wide spectrum of providers that furnish cardiovascular screening tests, the Department has changed §21.4301(3). Section 21.4301(3) as proposed provides that the Commissioner recognizes "an organization recognized by the Centers for Medicare and Medicaid Services" pursuant to the Insurance Code §1376.003(b). Section 1376.003(b) requires the Commissioner to recognize national organizations that certify laboratories to perform the screening tests for atherosclerosis and abnormal artery function that are set forth in the Insurance Code §1376.003(b)(1) and (2). The Department has changed §21.4301(3) to include "a certifying organization recognized by the Centers for Medicare and Medicaid Services" among those organizations that may certify a laboratory for purposes of the Insurance Code §1376.003. Additionally, new §21.4301 retains the proposed language identifying that the certification in question applies to a laboratory. New §21.4301 as changed therefore clarifies that there are three categories of national certifying organization that the Commissioner recognizes for purposes of the Insurance Code §1376.003: (i) the American College of Radiology; (ii) the Intersocietal Accreditation Commission; or (iii) a certifying organization recognized by the Centers for Medicare and Medicaid Services (CMS). This change clarifies that persons or entities directly recognized by CMS to perform the designated cardiovascular screening tests are not necessarily within the

scope of §21.4301. Rather, §21.4301 provides that the Commissioner recognizes those certifying organizations recognized by CMS to provide certification of laboratories for the performance of the subject screening tests. Read as a whole, §21.4301 as changed clarifies that the Commissioner recognizes organizations in the capacity of laboratory certification to perform the CT and IMT screening tests rather than in any other capacity. This interpretation reflects the statutory minimum coverage requirement concerning cardiovascular screening tests performed by a laboratory as provided in the Insurance Code §1376.003 without expanding the requirement in a manner not specified in the statute. The laboratories that will qualify to provide services pursuant to the minimum coverage requirement established in the Insurance Code §1376.003 will be those laboratories that are certified to perform screening tests for atherosclerosis and abnormal structure and function through CT scanning measuring coronary artery calcification or through ultrasonography measuring carotid IMT and plaque by : (i) The ACR; (ii) the IAC; or (iii) another certifying organization recognized by CMS. Health benefit plans may elect to provide additional coverage for screening tests for cardiovascular disease performed in settings other than that specified in the Insurance Code §1376.003 for purposes of minimum coverage requirements. However, such additional coverage is neither required under HB 1290 nor subject to the certification standard established in §1376.003. The Department further clarifies that new §21.4301 recognizes national organizations that may certify a laboratory for purposes of the minimum requirements specified in the Insurance Code §1376.003, as mandated by that section. New §21.4301 does not recognize specific standards that are utilized by

those national organizations. As such, future developments with respect to the certification standards used by the recognized organizations will not require additional rulemaking *per se*. The Department will, however, continue to monitor this issue to determine whether further rulemaking is required to address future developments in the certifications applicable to laboratories performing these screening services. Should such rulemaking become necessary, §1376.003 authorizes the Commissioner to undertake such rulemaking with respect to recognition of national certifying organizations for purposes of the minimum coverage requirements established in that section. Inclusion of a provision in the rule to that effect will not affect the underlying statutory authority and is not necessary. Finally, the term “provider” in general application includes not only physicians but also medical facilities. For this reason, reference to provider credentials in discussing certification of laboratories for purposes of §1376.003 is appropriate.

Reporting Requirement.

Comment: A commenter recommends that the Department require health plans to report to the Department by December 31, 2010, the number of providers that have been deemed to provide the screening services as well as the number of health plan members that have obtained the service. The commenter asserts that this information will assist the public and the legislature to understand the access that has been provided under HB 1290.

Agency Response: The Department disagrees with the suggested requirement. The suggested reporting requirement constitutes new subject matter and would improperly

impose a requirement not contemplated in the proposal. However, the Department will monitor to determine whether future rulemaking is required or whether future data collection activities with respect to access to this minimum coverage requirement are necessary.

5. NAMES OF THOSE COMMENTING FOR AND AGAINST THE SECTION.

For with change: The Society of Heart Attack Prevention and Eradication, SonoSite Inc.

Against: Advanced Center for the Prevention of Heart Attack and Stroke at the Grace Clinic.

6. STATUTORY AUTHORITY. The new section is adopted under the Insurance Code §1376.003(b) and §36.001. The Insurance Code §1376.003(b) provides that in order to qualify for the minimum coverage specified in §1376.003(b), the screening tests for atherosclerosis and abnormal artery structure and function must be performed by a laboratory that is certified by a national organization recognized by the Commissioner by rule. The Insurance Code §36.001 provides that the Commissioner of Insurance may adopt any rules necessary and appropriate to implement the powers and duties of the Texas Department of Insurance under the Insurance Code and other laws of this state.

7. TEXT.

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§21.4301. Recognition. The Commissioner recognizes the following organizations pursuant to Insurance Code §1376.003(b), which requires the Commissioner to recognize national organizations that certify laboratories to perform the screening tests for atherosclerosis and abnormal artery structure and function that are set forth in the Insurance Code §1376.003(b)(1) and (2):

- (1) the American College of Radiology;
- (2) the Intersocietal Accreditation Commission; or
- (3) a certifying organization recognized by the Centers for Medicare and

Medicaid Services.

IT IS THEREFORE THE ORDER of the Commissioner of Insurance that new Subchapter II, §21.4301 specified herein, concerning the recognition of national certifying organizations for noninvasive screening of cardiovascular disease, is adopted.