

**Louisiana State Board of Medical Examiners**  
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**\*\*\* STATEMENT OF POSITION \*\*\***

**SELF-REFERRED DIAGNOSTIC ULTRASOUND SCREENING**

**October 25, 2000**

In recent months, the Louisiana State Board of Medical Examiners (the “Board”) has received several inquiries for advisory opinions as to the legality, under applicable state law, of mobile ultrasound screening as made available and offered to the public at various locations. From such inquiries, consistent with notice of printed advertisements, the Board is given to understand that several firms are providing or seeking to provide such testing throughout the state; that such testing services are being offered to the public particularly for carotid vascular, abdominal aortic and peripheral arterial disease screening. Such inquiries—and the Board’s own investigation—suggest that mobile ultrasound units may function through various arrangements among owners/managers of the units, sponsoring hospitals, physicians and ultrasound technicians. Typically the personnel actually performing such tests function in the absence of physician presence and in most if not all instances with the individuals screened presenting themselves without a physician’s prescription, prior examination or referral. In such a context, the technician may act either wholly without physician authority, with ultrasound studies being interpreted on-site by the technician or processed for later interpretation by a physician. In other instances the technician may act pursuant to a standing protocol or “blanket” authorization of a physician who may be, but is not necessarily, licensed to practice medicine in Louisiana, for later physician interpretation. The issue presented by such operations, thus, is whether ultrasound screening and analyses constitutes the practice of medicine and may therefore be performed only by, or under the direct and immediate supervision of, a licensed physician.<sup>1</sup>

As defined by the Louisiana Medical Practice Act the scope of the “practice of medicine” explicitly encompasses “the examining, either gratuitously or for compensation, of any person . . . Whether such drug, instrument, force, or other agency or means is applied to or used by the patient or by another person,” for the purpose of diagnosing a bodily or mental condition. As a matter of law, accordingly, the Board believes there can be no doubt but that undertaking to perform and/or providing the results of ultrasound screening constitutes the practice of medicine. Strict application of this conclusion would, thus, constrain the Board in the discharge of its responsibility to safeguard the public health, welfare and safety against the “unauthorized and unqualified practice of medicine,” to take appropriate enforcement action against persons and firms who, through personnel other than licensed physicians, provide ultrasound screening to the public.

Such enforcement would, in fact, serve to ameliorate several concerns implicated by non-physician ultrasound screening. Paramount among these is the inability to ensure that performance of such studies are undertaken by individuals appropriately trained and qualified in proper technique and otherwise qualified to perform the procedure. Inasmuch as ultrasound

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<sup>1</sup>The Louisiana Medical Practice Act, LA. REV. STAT. ANN. §§37:1261-1291 (West 1988 & Supp.), prohibits the practice of medicine in this state by anyone who does not possess a license or permit duly issued by the Board.

technicians are neither licensed nor regulated by any agency in this state, we are not in a position to ensure that all technicians engaged in the performance of ultrasonography meet educational standards established on a national level. Furthermore, in the less than controlled environment than that of institutional or office settings, the quality of the equipment employed by mobile screening services may not be subjected to regular and periodic inspection and maintenance, which may contribute to inaccuracy in results. Inaccuracy or misdiagnosis of any degree, whether contributed to by the competency of technicians or the quality of the equipment, could have significant and serious consequences. The recipient of ultrasound screening results, for example, that report an obstruction in one of the areas screened might be subject to unnecessary anxiety and even medication, treatment and expense. Worse, if a negative screen were reported, that same individual might then consider himself as not being at risk for artery blockage or aneurysm and would not be motivated to seek proper medical treatment.

Thus, in the course of considering the issue, the Board has considered the relative medical benefits and risks attending the provision of ultrasound screening as described and otherwise. It could be argued that ultrasound procedures should only be performed following and pursuant to a medical history and correlative physical examination by a physician. The converse position is, of course, that such risks are overstated and that, in any event, the risks are acceptable when weighed against the benefit of ultrasound screening made more accessible by such operations which may detect potentially serious or even fatal conditions.

The Board first addressed itself to such operations in June of this year, following consideration of House Concurrent Resolution 82 of the 2000 Regular Session of the Louisiana Legislature, urging its cooperation with companies employing mobile ultrasound screening to develop guidelines permitting such practices with physician oversight and in a manner consistent with the law. In response to such resolution, the Board sought to identify and thereafter solicited proposals for its consideration to address the issue. After due consideration, the Board then determined that under controlling Louisiana law the legal capacity to administer diagnostic ultrasonography was contingent upon the on-site presence of an appropriately trained Louisiana licensed physician, who was responsible for the quality of the equipment and the diagnosis of all studies. Since then the Board has—at the further request of private parties, and on its own initiative—given reconsideration to its initial advisory ruling.

Because the Board's position may affect parties other than those with which the Board has communicated directly, and because inquiries concerning the Board's rulings in this area are recurring, the Board has concluded that it is timely and appropriate that its views on this subject be expressed in a formal Statement of Position. That is to say, that it is the Board's position and ruling that, as a matter of law, ultrasound screening services should satisfy the following conditions:

- (1) *Physician General Supervision.* The screening service should be provided under the general supervision of a physician, who is licensed and engaged in the practice of medicine in this state, who is qualified by education and training to conduct and interpret the tests offered and who is responsible and accountable to the Board for the service's compliance with each of the conditions enumerated below. Such physician may be employed as a medical director or serve as a consultant to the screening service.
- (2) *Information Provided.* No screening service or person administering such screens should undertake to interpret the clinical significance of screen results, render or express a medical diagnosis, or in any way suggest the necessity or appropriateness, or lack of necessity or appropriateness, of any form of treatment. Persons screened may be provided only with medically accurate

- written diagnoses concerning the significance of the screens offered and the results reported by the physician providing general supervision to the screening service or by a similarly qualified, licensed physician practicing medicine in this state.
- (3) *Referral.* All persons tested will be advised in writing of the necessity of appropriate follow-up with a physician if such is warranted by the screening results. All persons screened should be encouraged to provide the ultrasound results to their primary care physician.
  - (4) *Qualified Administration.* All screening should be performed only by ultrasonographers who are registered or registry eligible with the American Registry of Diagnostic Medical Sonographers, other nationally recognized certifying groups or who are otherwise properly qualified by education and training in accordance with nationally recognized standards in the application of ultrasound to the areas screened.
  - (5) *Instrumentation Quality Assurance.* Systems and equipment used for ultrasound screening should be of appropriate quality, properly maintained and periodically inspected by a person qualified and trained to do so. The physician providing general supervision for the screening service shall be responsible for quality control and ensuring the safe and proper operation of all equipment.
  - (6) *Truth in Advertising/Misleading Solicitation.* Announcement, promotion or solicitation of self-referral by ultrasound screening services, in literature or in any other form, must not overstate the potential benefit of such screening in an asymptomatic, self-referred population. For example, literature soliciting carotid ultrasound screening should not suggest that such screening will prevent strokes in asymptomatic individuals without appropriate modification of evidence-based, scientifically proven conventional risk factors such as high blood pressure, cigarette smoking, high blood cholesterol and diabetes mellitus. Promotional materials should also indicate that such screening does not replace an appropriate history, physical examination, laboratory testing and treatment by a physician or other appropriately licensed health care provider.
  - (7) *Noncompliance by Unlicensed Personnel.* An ultrasound technician or any other unlicensed individual who may perform ultrasound screening in a manner inconsistent with the Board's position may subject themselves to a suit for injunction by this Board<sup>2</sup> and/or to criminal prosecution.<sup>3</sup>
  - (8) *Noncompliance by a Physician.* A physician participant in such a relationship inconsistent with this Statement would be subject to suspension or revocation of licensure by this Board.<sup>4</sup>

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<sup>2</sup>LA. REV. STAT. ANN. §§37:1271, 1286 (West 1988 & Supp.).

<sup>3</sup>LA. REV. STAT. ANN. §37:1290.

<sup>4</sup>LA. REV. STAT. ANN. §37:1285A(18).