

Louisiana State Board of Medical Examiners
630 Camp Street, New Orleans, LA 70130
(504) 568-6820



***** STATEMENT OF POSITION *****

**Non-Physician Cholesterol Screening,
Clinical Laboratory Testing**

February 9, 1990

Digest of Statement

The performance of cholesterol level screening and other clinical laboratory analyses constitutes the practice of medicine under Louisiana law. When not performed by a physician in a medical office, but as made available at shopping malls, supermarkets, pharmacies and similar commercial locations, public cholesterol testing is often associated with critical deficiencies which compromise its safety and effectiveness. Infection, inaccurate and misleading results, and misinformation concerning the significance of results have been associated with such cholesterol testing services.

In the interest of the public health, welfare and safety, accordingly, the Louisiana State Board of Medical Examiners advises that public cholesterol screening should be: (1) performed only under the general supervision of a qualified physician; (2) operated and provided so as to ensure proper calibration of instruments and systems; (3) administered only by personnel properly qualified in the drawing of blood samples and proper sterile techniques, and the proper operation of testing instruments; (4) administered without interpretation of the clinical significance of test results or indication of the medical necessity or lack of necessity of any form of treatment, but with notice to persons submitting to such tests of the risk of falsely positive, falsely negative and anomalous results and that the clinical significance of results may be determined only by a physician in light of history and physical examination.

As an important element of an individual's health care, the Board encourages cholesterol screening by, or on the referral of, a qualified physician in conjunction with history and physical examination.

In recent months, the Louisiana State Board of Medical Examiners has received a number of inquiries as to the legality, under applicable state law, of cholesterol screening, blood tests, and other clinical laboratory analyses as made available and offered to the public at shopping malls, supermarkets, pharmacies, and similar commercial locations. From such inquiries, consistently with our own notice of printed advertisements, the Board is given to understand that a number of firms are providing such testing throughout the state; that such testing services may offer blood cholesterol level¹ analysis and/or a variety of other clinical laboratory tests;² that such tests are provided to the public generally, without the necessity of referral by a physician or other practitioner; that typically the personnel actually performing such tests—through the drawing of blood samples and operation of electronic instruments utilizing chemical reagents—are not physicians; and that the results of such tests are provided directly to the person tested. The issue presented by such operations, thus, is whether cholesterol and other blood testing and laboratory analyses constitutes the practice of medicine and may therefore be performed only by, or under the direct and immediate supervision, of a licensed physician.³

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 or material from any person” for the purpose of diagnosing a bodily or mental condition.⁴ The Board has consistently held in the past that this clause of the statutory definition embraces, among other things, clinical laboratory analyses of all types. As a matter of law, accordingly, the Board believes there can be no doubt but that undertaking to perform and provide the results of cholesterol blood levels and other blood tests 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 cholesterol level and other blood tests to the public.

Such enforcement would, in fact, serve to ameliorate several health concerns implicated by non-physician cholesterol and blood testing. The very act of drawing blood, of course, entails a risk of infection, transmittal of disease, or other injury if not performed by someone trained in proper sterile technique and otherwise qualified to perform the procedure. More significantly, with respect to lay cholesterol testing in particular, there are several difficulties and dangers which should and must be recognized.⁵

In the best of environments, cholesterol blood level measurements are subject to some degree of inaccuracy by virtue of imprecision (relating to reproducibility of results), improperly

¹*I.e.*, Total cholesterol, high-density lipoprotein (HDL) and/or low-density lipoprotein (LDL) cholesterol levels in milligrams per deciliter (mg/dL) of blood.

²*E.g.*, Triglycerides, Glucose, Hemoglobin, Blood Sugar/Diabetes, Uric Acid, Gamma GT.

³The Louisiana Medical Practice Act, LA. REV. STAT. ANN. §§ 37:1261-1291 (West 1988 & Supp. 1989), prohibits the practice of medicine in this state by anyone who does not possess a license or permit duly issued by the Board. Persons who engage in the practice of medicine in violation of such prohibition are subject to criminal penalties, La. Rev. Stat. § 37:1290, as well as injunctive action by the Board, La. Rev. Stat. § 37:1286.

⁴LA. REV. STAT. ANN. § 1262(1) (West 1988).

⁵The balance of this statement focuses particularly on cholesterol level screening. The observations made and conclusions reached by the Board are, however, generally applicable as well to other blood tests and clinical laboratory analyses.

calibrated systems or methodological errors by the person administering the test.⁶ One survey indicated that, even in the controlled environment of clinical pathology laboratories, nearly half of all laboratories produced results varying from true value by five percent or more with nearly 25% deviating by 10% or more.⁷ Perhaps needless to say, in the less controlled environment of cholesterol testing at retail storefronts, the risk of inaccurate results must be assumed to be at least as great, if not substantially greater. An apparently minor degree of inaccuracy, moreover, can have significant and serious consequences. With improperly calibrated systems, consistent negative or positive biases in results can in fact lead to misdiagnosis. A testing service, for example, that measures cholesterol with a method having a positive bias of 10% would report a value of 264 mg/dL for an individual with a true value of 240 mg/dL. In such an instance, the recipient of the result might be subject to unnecessary anxiety and even prolonged, if not life-long, dietary and medication treatment, unnecessarily. Worse, from a testing system having a similar degree of negative bias, the same individual would receive a falsely low result of 216 mg/dL. Such an adult might then consider himself as not being at risk by elevated cholesterol and would not be motivated to seek proper medical treatment.

Even given accurate results, cholesterol level measurements are subject to anomalies in a given individual over a relatively short span of time. And it should be acknowledged, finally, that cholesterol test results can ultimately be meaningful for diagnostic and treatment purposes only when interpreted in correlation with history and physical examination. Many if not all of these observations and concerns, of course, relate similarly to blood tests other than cholesterol measurement.⁸

Significantly, the Inspector General of the Department of Health and Human Services (HHS), which conducted an investigation of public cholesterol screening at the request of Congress, recently reported finding that the accuracy and usefulness of public cholesterol screening are compromised by poor quality assurance, inadequate on-site counseling, and lack of referral to a physician when appropriate.⁹ More particularly, the Inspector General observed that the qualifications and training of staff conducting public cholesterol screening may vary widely and include persons without any health care experience; that basic rules of hygiene are frequently disregarded; and that methods employed for collecting blood samples often impair the accuracy of results.¹⁰

In light of such concerns and others, and quite aside from legal considerations, some

⁶In this context, “precision” relates to reproducibility of results, while “accuracy” relates to agreement with true value. While the dangers of inaccuracy are somewhat obvious, imprecision can also be significant. As observed by two leading authorities, “[a]n analytical system with a 10% imprecision would mean that with 95% confidence limits . . . , values between 192 and 288 can be generated around a true value of 240 mg/dL” H. Naito, Ph.D., A. Hartmann, M.D., *Cholesterol Standardization*, at 4 (1988) [hereinafter *Cholesterol Standardization*]. Herbert K. Naito, Ph.D., is Chairman of the Laboratory Standardization Panel, National Institutes of Health Cholesterol Education Program; Alfred E. Hartmann, M.D., is Chairman of the Chemistry Resource Committee, College of American Pathologists.

⁷Such results are reported by the College of American Pathologists’ proficiency testing surveys from 5,000 participants in its Comprehensive Chemistry Survey. See *Cholesterol Standardization*, at 5.

⁸Inaccurate blood glucose values, by way of example, can directly affect diagnosis of diabetes.

⁹R. P. Kusserow, Inspector General, U.S. Dept. of Health & Hum. Services, PUBLIC CHOLESTEROL SCREENING (Nov. 1989) (draft) (cited hereinafter as OIG Report); see also Testimony of Richard P. Kusserow, Inspector General, Dept. of Health & Human Services before the Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business, on Public Cholesterol Screening (Nov. 27, 1989).

¹⁰Both the manner and timing of the blood sample collection are significant. Reliable cholesterol testing requires prior fasting, something irregularly achieved by public screening services. Squeezing, or “milking” a fingerstick, a technique common to the services inspected by OIG, can affect the accuracy of test results by diluting the sample and yielding a lower than normal result.

medical authorities, including those directly concerned with public health, have seriously questioned the propriety and value of nonphysician cholesterol and blood testing of the type which this Statement concerns. The Association of State and Territorial Public Health Laboratory Directors (APHLD), for example, while acknowledging that “[a]ppropriately performed tests accompanied by counseling and education can be of value in motivating the public to adopt life styles which promote health,” observes that “shopping mall and storefront laboratory testing can be a gross disservice to the American public when tests are not performed by trained personnel on quality controlled instrumentation and coordinated with one-on-one consultation.” As a result, APHLD has formally taken the position that as currently performed, it “does not support this type of...testing and strongly discourages it.”¹¹ Similar views have been expressed by other governmental and private health care concerns.¹² Similarly, the Inspector General, noting the “numerous shortcomings which compromise the safety and effectiveness of public screening,” and observing that the public is generally unaware of such shortcomings and hazards, has recommended that HHS should “discourage public cholesterol screening” which is unregulated, not conducted by health care professionals and otherwise does not meet the guidelines prescribed by the National Cholesterol Education Program.¹³ Strong and legitimate arguments, that is, can and have been made that an outright ban should be enforced against such nonphysician cholesterol/blood testing services.

It is, accordingly, the Board’s position that any such testing facility should satisfy the following conditions:

- (1) *Physician General Supervision.* The testing service should be organized and provided under the general supervision of a physician licensed 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 these conditions. Such physician may be employed or serve as a consultant to the testing service.
- (2) *Instrumentation Quality Assurance.* Systems and instruments used for cholesterol blood level and other blood tests should employ a method and be properly calibrated, and periodically checked for calibration, by a person qualified and trained to do so. The testing service should be able to achieve and to demonstrate and document achievement of reasonable precision and accuracy with respect to results reported.
- (3) *Qualified Administration.* The testing should be performed only by personnel properly qualified, by education and training, in the drawing of blood samples, proper sterile techniques, and the correct operation of testing instruments.
- (4) *Information Provided.* No testing service or person administering such tests should undertake to interpret the clinical significance of tests results,

¹¹Ass’n of State and Territorial Pub. H. Lab. Directors, Position Statement on Shopping Mall-Storefront Laboratory Testing Sites (1989).

¹²We note, for example, that the Florida Department of Health and Rehabilitative Services (HRS) has for some time sought to prevent such cholesterol testing at shopping malls and that, earlier this year, the Florida legislature enacted a Cholesterol Screening Act requiring direct supervision of cholesterol screening services by a licensed clinical laboratory or licensed physician and further requiring that a person or business that performs screening services be licensed by HRS. Similarly, we understand that the Michigan legislature is considering a bill prohibiting the testing of blood for serum cholesterol unless the test is ordered by a physician. A Louisiana parish medical society has also communicated with the Board, opposing such testing with reference to many of the health concerns expressed herein, as well as the fact that such testing constitutes the practice of medicine as a matter of law.

¹³OIG Report 14.

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 tested may be provided only with medically accurate written information concerning the significance and limitations of the tests offered and the test results reported. In the case of cholesterol testing, persons submitting to nonphysician-administered blood testing should be informed of the risk of falsely positive, falsely negative and anomalous test results and further informed that the clinical significance of test results, even if accurate, may be determined only by a physician in light of history and physical examination. Information equivalent to the following classifications may be provided to persons utilizing cholesterol blood level testing services:

Total Cholesterol (mg/dL)	LDL-Cholesterol (mg/dL)
< 200: Desirable	< 130: Desirable
200-239: Borderline/High	130-159: Borderline/High Risk
240: High	160: High Risk

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