

STATE OF NORTH DAKOTA

ATTORNEY GENERAL'S OPINION 98-F-27

Date issued: October 9, 1998

Requested by: Larry Isaak, Chancellor  
North Dakota University System

- QUESTIONS PRESENTED -

I.

Whether blood cholesterol screening tests conducted by North Dakota State University pharmacy students at pharmacy clinical sites are exempt from the licensure requirements of N.D.C.C. ch. 43-48 as tests performed for teaching or research.

II.

Whether blood cholesterol screening tests conducted by North Dakota State University pharmacy students at pharmacy clinical sites are exempt from the requirements of N.D.C.C. ch. 43-48 because they are screening tests for mass screening and done under appropriate supervision.

- ATTORNEY GENERAL'S OPINIONS -

I.

Blood cholesterol screening tests conducted by North Dakota State University pharmacy students at pharmacy clinical sites are not exempt from the licensure requirements of N.D.C.C. ch. 43-48 as tests performed for teaching or research because the test results may be used for health maintenance.

II.

Because the determination of whether blood cholesterol screening tests conducted by North Dakota State University pharmacy students at pharmacy clinical sites are exempt from the requirements of N.D.C.C. ch. 43-48 as mass screening tests done under appropriate supervision depends on the resolution

of factual issues on which I have insufficient information, I cannot issue an opinion on whether the tests are exempt.

- ANALYSES -

I.

NDSU pharmacy students at nine pharmaceutical care location sites in North Dakota community pharmacies collect the results from between 2,000 and 2,500 blood cholesterol screening tests annually. Should a test result indicate a problem with cholesterol, HDL or triglyceride levels, participants are referred to their primary care physician. The screening tests done by the pharmacy students are an integral part of the students' required pharmaceutical care rotations.

At the inception of the program, the College of Pharmacy obtained approval of the NDSU Institutional Review Board to utilize the data for research purposes. The data has been analyzed and used in connection with two published articles and three abstracts presented at state and national professional meetings. One of the pharmaceutical care sites is involved in a research project, funded by a pharmaceutical company, intended to implement screening and monitoring services for patients under treatment for lipid disorders.

N.D.C.C. ch. 43-48 establishes the North Dakota Board of Clinical Laboratory Practice (Board) for the purpose of licensing and regulating clinical laboratory personnel. N.D.C.C. § 43-48-02 provides that "[n]o person may practice as a clinical laboratory scientist or a clinical laboratory technician unless the person is the holder of a current license issued by the board, or is exempt from licensure." Subsection 3 of section 43-48-04 provides that the provisions of chapter 43-48 do not apply to "[p]ersons performing clinical testing for teaching or research, provided that the results of any examination performed in such laboratories are not used in health maintenance, diagnosis, or treatment of disease."

Health maintenance includes actions taken to keep health in proper condition or to prevent a relapse. The American Heritage Dictionary 757 (2d coll. ed. 1991); Webster's Medical

Desk Dictionary 405 (1986). Although used for teaching or research, the clinical tests in question are also performed to provide the recipients information regarding their cholesterol, HDL and triglyceride levels. Some individuals, particularly those with known medical problems, may use the results of the tests to determine appropriate self care or whether to consult a physician.

Thus, some individuals receiving the test may use the results for health maintenance. I cannot conclude as a matter of law that the test results of the blood cholesterol screening tests conducted by pharmacy students are not used for health maintenance. Therefore, it is my opinion that blood cholesterol screening tests conducted by North Dakota State University pharmacy students at pharmacy clinical sites are not exempt from the licensure requirements of N.D.C.C. ch. 43-48 as tests performed for teaching or research because the test results may be used for health maintenance.

## II.

N.D.C.C. § 43-48-04(7) provides that the provisions of chapter 43-48 do not apply to "[p]ersons performing screening tests for mass screening under appropriate supervision." Thus, for testing to be exempt under the mass screening exemption, three requirements must be met: (1) the persons must be performing screening tests; (2) screening tests must be for mass screening; and (3) the persons performing the tests must be under appropriate supervision. Id. Each of these requirements must be met in order for the exemption from licensure to apply.

"Screening test" is defined in N.D.C.C. § 43-48-01(8) to mean "a test measuring only the approximate value of the analyte being tested and not used for diagnosis." The request letter states the test being administered is a blood cholesterol "screening" test. One would assume the term "screening" is used because the test only measures the approximate value of the analyte being tested. However, no information has been provided regarding whether the test measures specific or approximate values. If specific values are obtained, the tests are not "screening tests," and the exemption would not apply. If, on the other hand, the values are approximate, the tests are "screening tests," and the first prong of the

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definition of "screening test" is met. However, because that information was not provided, that determination cannot be made at this time.

Whether particular tests meet the second prong of the definition of "screening test," that is, the results are not used for diagnosis, is a factual question. In making the factual determination, it is essential to understand the meaning of the term "diagnosis." N.D.C.C. ch. 43-48 does not define the term "diagnosis." The term must, therefore, be understood in its ordinary sense. N.D.C.C. § 1-02-02. As generally understood, "diagnosis" is the "act or process of identifying or determining the nature of a disease through examination" or the "opinion derived from such an examination." The American Heritage Dictionary 391 (2d coll. ed. 1991). See also State v. Horn, 422 P.2d 172, 177 (Ariz. App. 1966) ("['Diagnosis'] is the act or art of recognizing the presence of disease from its symptoms.").

Thus, if the test results are used to make an ultimate conclusion regarding the testee's condition, the test is not a screening test. On the other hand, if the results of the tests are simply used to indicate possible concerns and, therefore, a need for a thorough medical examination, the test is not being used for a diagnosis. See State v. Evans, 424 S.E.2d 512 (S.C. App. 1992) (a "preliminary indication" is merely a sign of something, whereas a "diagnosis" is a determination or a conclusion drawn from analysis).

The request letter states the results of the screen tests are not used by students in "diagnosis or treatment of disease." According to your letter, all persons having elevated values are referred to their physicians for further evaluation. Based upon these facts, the conclusion can be made that the tests are being used to indicate possible concerns and not used for diagnosis. Accordingly, the second prong of the definition of "screening test" is met.

N.D.C.C. § 43-48-03(7) requires that, in addition to being a screening test, the test must be performed for mass screening. "Mass screening" is not defined in N.D.C.C. ch. 43-48. As generally understood, the term "mass" means "[a] large but nonspecific amount or number." The American Heritage Dictionary 770. Thus, a mass screening is "[d]irected at or

reaching a large number of people" or "attended by a large number of people." Id.

Whether a particular screening test is a mass screening is a factual question. However, a screening test would not constitute a mass screening unless it was done on a large scale and involved a large number of people. Typically, a mass screening test would be open to all members of the public or all members of a large identifiable group, such as elementary school students, mine workers, etc.

According to the request letter, at present time the screening tests are offered at nine pharmaceutical care rotation sites in community pharmacies across North Dakota. Each pharmacist preceptor advertises the screening services offered by the pharmacy in the local news media and displays appropriate signs in the pharmacy. Outreach programs are held during which screening services are offered by the students and preceptors at various community sites, such as churches, nursing homes, etc. The screening test is offered to all members of the public, with approximately 2,000 to 2,500 people being tested per year. Based upon these facts, the test is performed for mass screening.

N.D.C.C. § 43-48-03(7) also requires that a mass screening test be performed under "appropriate supervision" in order to be exempt. The chapter does not define what constitutes "appropriate supervision." Since one could make any number of reasonable arguments about what constitutes "appropriate supervision," the statute is ambiguous, and reference to extrinsic aids to interpret the statute is appropriate. See Northern X-ray Co., Inc. v. State ex rel. Hanson, 542 N.W.2d 733, 735 (N.D. 1996).

N.D.C.C. § 1-02-39 lists a number of extrinsic aids which may be used in construing an ambiguous statute, including the statute's legislative history. "[T]he cardinal rule of statutory interpretation is that the interpretation must be consistent with legislative intent and done in a manner which will accomplish the policy goals and objectives of the statutes." O'Fallon v. Pollard, 427 N.W.2d 809, 811 (N.D. 1988).

N.D.C.C. ch. 43-48 was enacted in 1989. 1989 N.D. Sess. Laws ch. 538. During its consideration by the House Committee on Human Services and Veterans Affairs, the committee debated the exemption for mass screenings at some length. Hearing on S. 2371 before the House Comm. on Human Services and Veterans Affairs, N.D. 51<sup>st</sup> Leg. (March 23, 1989). In fact, the exemption for mass screenings was actually amended out of the act at one point. Later in the hearing, the exemption was added back into the act, with the addition of the "under appropriate supervision" language. Id. In discussing the "appropriate supervision" language, the committee decided that the determination about what constitutes "appropriate supervision" should be left to the Board. Id. (Statements of Rep. Rydell and Rep. Olson). Accordingly, the Board has the duty and privilege of determining what constitutes "appropriate supervision" on a case-by-case basis.

The request letter states that the North Dakota State University College of Pharmacy has previously asked the Board whether the tests are exempt as mass screening tests done under appropriate supervision. The Board replied that the tests were not exempt. Whether the Board considered the question of "appropriate supervision" is not clear from the materials included with the request letter. As such, the College of Pharmacy may need to make a second request to confirm the basis on which its earlier request was denied.

In conclusion, whether the proposed tests are exempt from the licensing requirements of N.D.C.C. ch. 43-48 as mass screening tests done under appropriate supervision depends on the resolution of several issues. If the information obtained by the tests measures only the approximate value of the analyte being tested and the tests are being done under appropriate supervision as determined by the Board, then the tests are exempt. However, if either of those criteria are not met, the tests are not exempt from the licensing requirement. Because that determination depends on the resolution of factual issues on which I have insufficient information, I cannot issue an opinion on whether the tests are exempt.

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This opinion is issued pursuant to N.D.C.C. § 54-12-01. It governs the actions of public officials until such time as the questions presented are decided by the courts.

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ATTORNEY GENERAL

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