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91033

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SUBJECT: Defining Home Testing as an Exception to Laboratories Regulated Under the Clinical Laboratories Certification Act.

REQUESTED BY: Gregg F. Wright, M.D., M.Ed., Director of Health

WRITTEN BY: Don Stenberg, Attorney General
Marilyn B. Hutchinson, Assistant Attorney General

You have asked several questions about your rule-making authority under the Clinical Laboratories Certification Act, Neb.Rev.Stat. §§ 71-6801 to 71-6831 (Reissue 1990).

1. What are the guidelines for standards for approving tests for home use?

A. You are directed to establish "reasonable standards in the public interest" governing approval of tests for home use. Neb.Rev.Stat. § 71-6830(7). The Legislature declared in Neb.Rev.Stat. § 71-6802 "that the people of Nebraska are entitled to receive the highest level of competency, reliability, and accuracy that may be expected from clinical laboratories." (Emphasis added.) The Legislature then required in Neb.Rev.Stat. § 71-6816 that such laboratories be certified as meeting standards which assure that they meet those levels. However, the Legislature excluded from the definition of a "laboratory" those locations where home tests are given by oneself, one's family or someone acting in lieu of one's family. When a person uses a home test under those circumstances it is reasonable to assume the person tested is not expecting the same level of competency, reliability and accuracy as from a certified clinical

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laboratory. Thus it may be "reasonable" to accept a lower level of competency, reliability and accuracy from a home test than from a test performed in a clinical laboratory. It may be "reasonable" in the public interest to emphasize convenience and accessibility to the test, particularly a test that must be administered frequently, in exchange for some assumption of risk by the person tested.

In developing the federal standards for clinical laboratories the Secretary of Health and Human Services must consider:

> (A) the examination and procedures performed and the methodologies employed,
>
> (B) the degree of independent judgment involved,
>
> (C) the amount of interpretation involved,
>
> (D) the difficulty of the calculations involved,
>
> (E) the calibration and quality control requirements of the instruments used,
>
> (F) the type of training required to operate the instruments used in the methodology, ...

42 U.S.C. §263.a(f)(2). Those same factors may be reasonable standards for reviewing tests for approval for home use if they are considered in light of the need for a test that is reasonably safe for use in a residential setting by untrained persons, as discussed below.

B. A "home" is a place where one lives; residence; habitation. American Heritage Dictionary of the English Language. Thus the test must be one that can be performed safely in a residential setting.

C. The test is to be performed by oneself, one's family or someone acting in lieu of one's family. A "family," in descending order of usage, consists of parents and their children; persons related by blood or marriage, relatives, kinsfolk; lineage; all the members of a household, those who share one's domestic home. "In lieu of" is defined as in place of, instead of. Id.

Thus the test must be one that can be performed safely by persons with no special training or skills.

D. "Standards of the Food and Drug Administration may be used as the basis for such standards." Neb.Rev.Stat. § 71-6830(7). Such a statement raises the specter of improper delegation of legislative authority because it does not specify which regulations you are to use and it appears to give you discretion whether to use them and, if so, to pick and choose which standards from such regulations you will adopt. See Lincoln Dairy Co. v. Finnigan, 170 Neb. 777, 104 N.W.2d 227 (1960).

However, such an objection is academic in this situation because there apparently are no FDA regulations setting standards for approval of home tests. In fact, the federal law prohibits any person from soliciting or accepting materials derived from the human body for laboratory examination unless there is a laboratory certificate in effect covering such examination or procedure. 42 U.S.C. §263a.(b).

Since avoiding compliance with federal law was one of the purposes of the Nebraska act, according to the legislative history, but not expressed in the act, the requirements under state law must be equal to or more stringent than they are under federal law. 42 U.S.C. 263a.(p). Thus the exclusion in Neb.Rev.Stat. § 71-6810 for home testing must be narrowly drawn if that objective is to be met.

2. May the regulations make direct reference to FDA standards, incorporate them by reference or set them out as your own standards?

Yes. A rule you adopt is valid against any person five days after it has been filed with the Secretary of State. Neb.Rev.Stat. § 84-906 (Reissue 1987). Thus unless any FDA standards you want to enforce as part of your rule are already on file with the Secretary of State as part of another rule, they must be set out in your rule and regulations or attached thereto and incorporated therein by reference.

3. May the department give deemed status as approved home tests to tests approved by the FDA?

No. Giving deemed status to such tests would delegate to the FDA the determination of whether the criteria were met. The state legislature has no power to delegate any of its legislative powers to any outside agency such as the Congress of the United States. Smithberger v. Banning, 129 Neb. 651, 262 N.W. 492 (1935). If the FDA approved tests specifically for home use, then the FDA standards and your standards would be the same only if you did not adopt any standards in addition to the FDA standards and if the

FDA standards were not amended after you incorporated them into your rule.

However, that objection is also academic because the FDA approves tests for safety and efficacy without reference to where they will be used. See 21 C.F.R.1 Part 814. You may require a test to be safe and effective as evidenced by such approval or by exemption from such approval before you will approve it for home use. However, such approval or exemption from approval by the FDA will not necessarily make a test appropriate for home use. There are other criteria which must be met, as discussed above.

4. What criteria may be used to determine if someone is acting in lieu of one's family?

The exclusion of some locations from the definition of a laboratory in Neb.Rev.Stat. § 71-6810 has the effect of exempting such locations from certification as laboratories. Statutory exemptions are strictly construed. See, e.g., Paxton & Hershey Irrigation Co. v. Farmers & Merchants Irrigation Co., 45 Neb. 884, 900, 64 N.W. 343 (1895), and State ex. rel. Halloran v. Hawes, 203 Neb. 405, 411, 279 N.W.2d 96 (1979). Strict construction in this case will also minimize the risk of federal regulation, as discussed above.

From the definitions of "family" and "home" set out above, it is clear that the place where the exclusion applies is a residential setting and the person administering the test is either someone residing there or, if not, is someone related by blood or marriage to the person tested. (It is like the exemption from licensing as an electrician of a person doing his own electrical work with a friend to help him.)

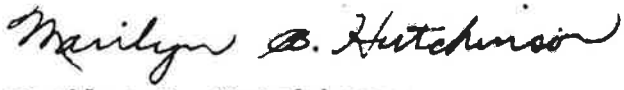
The helper will not necessarily have any special training or skills. In construing a statute, no word should be rejected as meaningless or superfluous. Pettigrew v. Home Insurance Co., 191 Neb. 312, 314, 214 N.W.2d 940 (1974). Thus, the range of permissible helpers is broadened by the addition of "someone acting in lieu of one's family." However, it is also a rule of statutory construction that "[w]here an enumeration of specific things is followed by some more general word or phrase, such general word or phrase is to be held to refer to things of the same kind." 19 C.J. 1255, quoted in State v. Bone Creek Township, 109 Neb. 202, 204, 190 N.W. 586, 587 (1922). Thus the person acting in lieu of one's family must be someone who, like one's family, is also not a professional tester or at least is not acting in that relationship to the person being tested.

5. May testing under the exclusion in Neb.Rev.Stat. § 71-6810 be by one's friends, a house parent in a group home, visiting nurses, or personnel in a nursing home or other employees of health care providers?

Yes, by one's friends or a house parent in a group home. No, by the others.

Sincerely yours,

DON STENBERG
Attorney General



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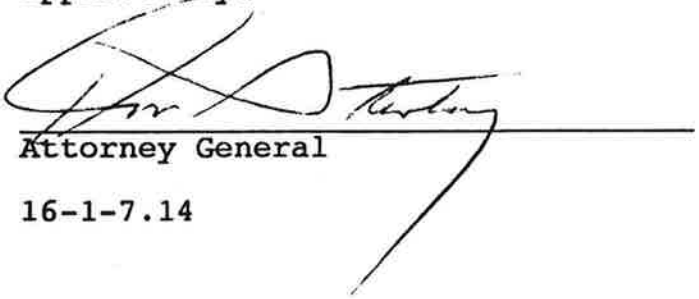

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