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JON BRUNING
ATTORNEY GENERAL

#04026

SUBJECT: Interpretation of Neb. Rev. Stat. § 71-1,104.01 Pertaining to Predictive Genetic Testing

REQUESTED BY: Richard Raymond, Chief Medical Officer
Health and Human Services System

WRITTEN BY: Jon Bruning, Attorney General
Lynn A. Melson, Assistant Attorney General

You have requested the opinion of this office regarding the interpretation and application of the statute governing consent for predictive genetic testing, Neb. Rev. Stat. § 71-1,104.01 (2003). Nebraska law requires physicians to obtain written informed consent before ordering predictive genetic tests. The Nebraska Department of Health and Human Services is required to develop a model informed consent form and has promulgated a form as part of 181 NAC 5. A patient who signs such a form is barred from subsequently bringing a civil action for damages for failure to obtain informed consent against the physician who ordered the predictive genetic test.

You state that the interpretation of § 71-1,104.01 has been raised as an issue by physicians practicing in Nebraska "who have a concern that this law raises the risk of liability for failure to inform for what would otherwise be considered routine medical tests, or tests for which they would not ordinarily use a 7 page consent form." We must first point out that

we answer your questions in the context of the Department's role in interpreting this statute and promulgating appropriate regulations. We are not authorized to provide legal opinions to private citizens and are not attempting to speak to the potential liability of Nebraska physicians. The physicians may wish to consult their own attorneys regarding potential liability.

We will first review the relevant statutory language which appears to be causing some confusion. The term genetic test is defined at Neb. Rev. Stat. § 71-1,104.01(6)(b), in part, as...

> "Tests of tissues, proteins, and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition. Genetic test does not include a routine analysis, including a chemical analysis, of body fluids or tissues unless conducted specifically to determine a heritable or somatic disease-related genetic condition..."

A predictive genetic test is defined at Neb. Rev. Stat. § 71-1,104.01(6)(c), in part, as...

> "Predictive genetic test means a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype. Predictive genetic test does not include diagnostic testing conducted on a person exhibiting clinical signs or symptoms of a possible genetic condition..."

It is the predictive genetic test which now requires use of the seven page model informed consent form adopted by the Department in 181 NAC 5. In your request letter you have set out two possible interpretations of the statutory language and asked for our opinion on which of the two interpretations is most consistent with the statute. We set out your two interpretations below.

Interpretation 1)

> An example of this would be when a patient's family history indicates a patient has diabetes, but the child has no signs or symptoms of problems with blood sugar regulation. The physician orders a glucose test to check the child's blood sugar. The child then is identified to have Diabetes type 1 which is an inherited disease. The physician's concern is that the glucose test could be considered

> a predictive genetic test. Another example would be the child with a family history of high cholesterol. The physician orders a cholesterol level, which comes back in a borderline range-not diagnostic of the disorder but in a range that one could not rule out familial hypercholesterolemia. The physician follows with advice on diet and exercise to avoid the potential negative outcomes of familial hypercholesterolemia. Again, the concern is that the cholesterol test could be interpreted as a predictive genetic test. One problem is that almost every disorder or disease has at least some genetic element to it and could be considered a "genetically related disease or disability."

Interpretation 2)

> An alternate interpretation of the law using the above glucose test example would be that absent signs or symptoms in the patient, the "family history" is the element that is "predictive", and the glucose test is clinically indicated or "diagnostic." A scenario that might demonstrate this is when the child has no signs or symptoms but has a parental family history of diabetes. The glucose test is ordered and comes back elevated. The high blood sugar now becomes a "sign". Any further testing, to look for the genes most commonly associated with Diabetes Type 1 also would not fall into the predictive genetic testing category because the child now has exhibited "signs or symptoms" of the disorder. However, in a similar situation where the child's glucose test comes back negative, any further testing to look for the genes most commonly associated with Diabetes Type 1 would fall into the predictive genetic testing category because the child still had no signs or symptoms of the disorder.

As the statutory definitions and exclusions cannot take into account every factual situation which may arise, it is not possible to predict with any certainty exactly which medical tests may be considered predictive genetic tests by a court. The definitions of both genetic test and predictive genetic test appear to be drafted with the intent to exclude most routine analysis and diagnostic testing. It also appears that the intent is to require use of the informed consent form only for those genetic tests ordered specifically for the purpose of predicting or determining whether a patient, who has no signs or symptoms of a possible genetic condition, has or will develop a particular genetic condition. In addition, while our review of the legislative history of § 71-1,104.01 was of no assistance in determining exactly which tests may be considered predictive genetic tests, we do note that the introducer of LB 432, Laws 2001 stated that the definitions were intended to be very narrow. Committee Records on LB 432, 97th Neb. Leg., 1st Sess. 8-9 (January 29, 2001). Therefore, in our view, the second interpretation which you have provided is the more plausible.

There is a general rule of statutory construction that the interpretation of a statute given by an administrative agency to which the statute is directed is entitled to weight. You have indicated that the Department believes that the second interpretation is more consistent with the language in the statute. To the extent that the Department consistently takes that position or expresses that position through rules and regulations or otherwise, a court is likely to accord some deference to the Department's interpretation and application of the statute. *Metropolitan Utilities Dist. v. Balka*, 252 Neb. 172, 560 N.W.2d 795 (1997); *Vulcraft v. Karnes*, 229 Neb. 676, 428 N.W.2d 505 (1988). "Although construction of a statute by a department charged with enforcing it is not controlling, considerable weight will be given to such a construction, particularly when the Legislature has failed to take any action to change such an interpretation." *Affiliated Food Co-op., Inc. v. State*, 259 Neb. 549, 556, 611 N.W.2d 105, 110 (2000).

Sincerely,

JON BRUNING
Attorney General

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Assistant Attorney General

APPROVED:

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9-204-24