NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES NOTICE OF PUBLIC HEARING

October 17, 2019 1:00 p.m. Central Time Gold's Building, Room 534 1033 O Street, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 177, Chapter 5 of the Nebraska Administrative Code (NAC) – *Fees for Department Laboratory Tests and Services.* The regulation establishes the formulas for setting the analytical fees for laboratory tests and services and payment responsibility for testing at the Nebraska Public Health Environmental Laboratory. The proposed changes update the definitions in the regulation to comply with Neb. Rev. Stat. § 71-5301 and remove duplicative statutory language from the regulations.

Authority for these regulations is found in <u>Neb. Rev. Stat.</u> § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services		
Title: 177	Prepared by: Mary Boden	
Chapter: 5	Date prepared: 3/6/19	
Subject:Fees for Dept. Lab Tests & Services	Telephone: 402-471-8441	

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(🖂)	(🖂)	(🛛)
Increased Costs	(🗆)	(🗆)	(🗆)
Decreased Costs	(🗆)	(🗆)	(🗆)
Increased Revenue	(🗆)	(🗆)	(🗆)
Decreased Revenue	(🗆)	(🗆)	(🗆)
Indeterminable	(🗆)	(🗆)	(🗆)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

•

DRAFTNEBRASKA DEPARTMENT OF05-06-2019HEALTH AND HUMAN SERVICES

177 NAC 5

TITLE 177 HEALTH/LABORATORY SERVICES

CHAPTER 5 FEES FOR DEPARTMENT LABORATORY TESTS AND SERVICES

<u>001.</u> <u>SCOPE AND AUTHORITY</u>. These regulations establish formulas for fees for laboratory tests and services and responsibility for payment pursuant to Nebraska Revised Statutes (Neb. Rev. Stat.) §§ 71-2619 to 71-2621, 71-5301, and 71-5306.

002. DEFINITIONS. Definitions set out in Neb. Rev. Stat. §§ 71-5301 and the following apply to this chapter:

<u>002.01</u> CHAIN OF CUSTODY. The documentation and other activities done to ensure the identity of a sample and to ensure that no substantial change has taken place in the sample to make it misleading. It includes all those activities that protect the integrity of the sample.

<u>002.02 ELECTIVE TEST.</u> A drinking water sample test which is performed for a reason other than to meet the public water system testing requirements found in Title 179.

<u>002.03</u> EQUIPMENT. Any tool, instrument, appliance, or utensil necessary to perform the task of analyzing laboratory samples which has a life expectancy greater than two years.

<u>002.04</u> SAMPLE. A representative portion of any substance submitted to the laboratory for testing.

<u>002.05 TEST.</u> The application of prescribed procedures designed to identify or measure the microbiological, chemical, radiological, or physical characteristics of materials and substances.

<u>003.</u> <u>COMPONENTS OF FEES IN THE FORMULAS.</u> The following are the components used in determining fees.

003.01 COST OF LABOR. The cost of labor is equal to 3 times the cost of the average salary and benefits of Department laboratory employee(s) who conduct the analysis for the period of time required to complete the test. The multiplier is used to account for employee time spent on laboratory related tasks.

<u>003.02</u> EQUIPMENT COST. Equipment cost is equal to the cost of the equipment divided by the life expectancy of the equipment plus the cost for maintenance and repairs.

003.03 MATERIAL COST. Material cost includes the costs for disposable equipment, reagents, and other items having a life expectancy of less than 2 years.

003.04 OVERHEAD COST. Overhead cost includes actual expenses not chargeable to a particular part of the work or product.

003.05 SAMPLE COLLECTION KIT COST. Sample collection kit cost is the cost associated with the container and chemicals for preservation of samples required to take samples relating to the testing of drinking water, environmental samples, and blood alcohol.

003.06 SHIPPING COST. Shipping cost includes all costs associated with the sample collection kits, mailing containers, sample collection forms and instructions, labor, cost of postage or transportation, and mailroom equipment and anything else necessary to carry out the function of shipping.

003.07 CHAIN OF CUSTODY COST. Chain of custody cost include all costs associated with the documentation and maintenance of samples.

<u>004.</u> FORMULAS AND METHODS FOR DETERMINING FEES. The following formulas and methods shall be used to establish fees for performing laboratory tests and services:

- (A) <u>The formula for shipping is Fee = Shipping Cost + Overhead;</u>
- (B) The formula for testing samples of blood for alcohol level is: Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody Estimated Number of Tests
- (C) <u>The formula for testing routine drinking water samples is:</u> <u>Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody</u> Estimated Number of Tests
- (D) The formula for testing environmental samples is: Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody Estimated Number of Tests
- (E) The fees for elective tests are determined using the formula for other similar samples.
- (F) <u>The fee for requests for tests not otherwise covered by this chapter will be the actual costs incurred by the Department.</u>
- (G) If the Department contracts with another laboratory to perform a test, the fee will be the contracted cost plus any related expenses the Department incurs.
- (H) If a request is made to assign higher priority to testing specific samples, and the laboratory workload is rescheduled to accommodate this request, any additional cost for doing so will be added to the fee otherwise determined by this chapter.

<u>005.</u> <u>RESPONSIBILITY FOR PAYMENT.</u> Each person or entity submitting a sample for analysis shall identify who is responsible for paying the fee when requesting a test.

TITLE 177 HEALTH/LABORATORY SERVICES

CHAPTER 5 FEES FOR DEPARTMENT LABORATORY TESTS AND SERVICES

<u>5-001 SCOPE AND AUTHORITY</u>: These regulations establish formulas for fees for laboratory tests and services and responsibility for payment. The authority is found in <u>Neb. Rev. Stat.</u> §§ 71-2619 to 71-2621, 71-5301, and 71-5306.

5-002 DEFINITIONS

<u>Chain of Custody</u> means the documentation and other activities done to ensure the identity of a sample and to ensure that no substantial change has taken place in the sample to make it misleading. It includes all those activities that protect the integrity of the sample.

Department means the Department of Health and Human Services Regulation and Licensure.

<u>Elective test</u> means a drinking water sample test which is performed for a reason other than to meet the public water system testing requirements found in Title 179.

<u>Equipment</u> means any tool, instrument, appliance, or utensil necessary to perform the task of analyzing laboratory samples which has a life expectancy greater than two years.

<u>Person</u> means any individual, firm, partnership, limited liability company, association, company, corporation, political subdivision, or other entity.

<u>Public water system</u> has the definition found in the Nebraska Safe Drinking Water Act, <u>Neb. Rev.</u> <u>Stat.</u> §71-5301.

<u>Sample means a representative portion of any substance submitted to the laboratory for testing.</u>

Shipping means conveying from one location to another.

<u>Test</u> means the application of prescribed procedures designed to identify or measure the microbiological, chemical, radiological, or physical characteristics of materials and substances.

5-003 COMPONENTS OF FEES IN THE FORMULAS

Where: Cost of Labor = 3 times the cost of the average salary and benefits of Department Laboratory employee(s) who conduct the analysis for the period of time required to complete the test. The multiplier is used to account for employee time spent

 on laboratory related tasks such as professional training and certification, quality assurance, documentation and reporting, and equipment calibration and cleaning. 		
Equipment Cost = Cost of Equipment + Maintenance + Repairs Life Expectancy of Equipment		
Materials cost includes disposable equipment, reagents and other items having a life expectancy of less than 2 years.		
 Overhead costs are the business expenses not chargeable to a particular part of the work or product, such as rent, utilities, travel, administration and computers. 		
Sample collection kit cost means all costs associated with the container and chemicals for preservation of samples required to take samples relating to testing of drinking water, environmental samples and blood alcohol.		
Shipping cost includes all costs associated with the sample collection kits, mailing containers, sample collection forms and instructions, labor, cost of postage or transportation, and mailroom equipment and anything else necessary to carry out the function of shipping.		
Chain of Custody costs include all costs associated with the special documentation and maintenance of samples.		
5-004 FORMULA FOR DETERMINING SAMPLE COLLECTING FEES		
5-004 FORMULA FOR DETERMINING SAMPLE COLLECTING FEES		
5-004_FORMULA FOR DETERMINING SAMPLE COLLECTING FEES ———————————————————————————————————		
Fee = Shipping Cost + Overhead		
Fee = Shipping Cost + Overhead <u>5-005_FORMULA FOR DETERMINING BLOOD ALCOHOL SAMPLES TESTING</u> <u>Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead +_Chain of Custody</u>		
Fee = Shipping Cost + Overhead <u>5-005_FORMULA FOR DETERMINING BLOOD ALCOHOL SAMPLES TESTING</u> <u>Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead +_Chain of Custody</u> <u>Estimated Number of Tests</u>		
Fee = Shipping Cost + Overhead 5-005_FORMULA FOR DETERMINING BLOOD ALCOHOL SAMPLES TESTING Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead +_Chain of Custody Estimated Number of Tests 5-006_FORMULA FOR ESTABLISHING FEES FOR ROUTINE DRINKING WATER SAMPLES Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody		
Fee = Shipping Cost + Overhead 5-005_FORMULA FOR DETERMINING BLOOD ALCOHOL SAMPLES TESTING Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead +_Chain of Custody Estimated Number of Tests 5-006_FORMULA FOR ESTABLISHING FEES FOR ROUTINE DRINKING WATER SAMPLES Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody Estimated Number of Tests		
Fee = Shipping Cost + Overhead 5-005_FORMULA FOR DETERMINING BLOOD ALCOHOL SAMPLES TESTING Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead +_Chain of Custody Estimated Number of Tests 5-006_FORMULA FOR ESTABLISHING FEES FOR ROUTINE DRINKING WATER SAMPLES Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody Estimated Number of Tests 5-007_FORMULA FOR ESTABLISHING FEES FOR ENVIRONMENTAL SAMPLES TESTING Fee = Labor Cost + Materials Cost + Equipment Cost + Overhead + Chain of Custody Estimated Number of Tests		

- <u>5-008.02</u> Additional Fees: Special requests, such as requests for samples to be tested at another laboratory to obtain a second opinion, will be charged at actual costs incurred by the Laboratory.
- <u>5-008.03 Fees for Contracted Tests:</u> If the Department Laboratory contracts with another laboratory to perform certain tests, the fee will be the contracted cost plus any related expenses the Department Laboratory incurs.
- <u>5-008.04 Expedited Service Fee:</u> If a request is made to assign higher priority to testing specific samples, and the laboratory workload is rescheduled to accommodate this request, any extra cost will be added to the listed fee. Extra cost may include overtime work and/or the cost of referring work to another laboratory.

<u>5-009 RESPONSIBILITY FOR PAYMENT:</u> Each sample submitted for analysis shall identify the person responsible for paying the appropriate fee.

<u>5-010 OWNER RESPONSIBILITY:</u> The owner of the public water system is responsible for collecting and transmitting samples in containers provided by the laboratory and at times prescribed by the laboratory. Delay or damage occurring prior to receipt of the samples by the laboratory will require submission of an additional sample.

Transmittal Form Proposed Regulations DHHS Division of Public Health

NAC Title and Chapter(s): _Title 177 NAC 5_

Subject: _Establish fees for department laboratory tests and services___

Legislative bills associated with these proposed regulations, if any: <u>NA</u>

State law requires that proposed regulations stemming from a legislative bill must have a public hearing within one year of the effective date of the legislative bill. The public hearing deadline for these proposed regulations is: _____

MO/DA/YEAR

If there is another relevant deadline or other reason for urgency associated with these proposed regulations, please indicate so here, along with a specific explanation of the source of the deadline or reason for urgency:

Prepared by: Mary Boden, Lab Manager Date: 3/6/19

Designated Contact: _Sue Medinger, Administrator, 4	02-471-0191
Name/Title/Phone	
Fiscal and Budget Impact Reviewed by Financial Services:	5/1/2019
Signature	Date