DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Laboratory Service Fees

2) Code Citation: 77 Ill. Adm. Code 475

3)

Section Numbers:	Proposed Action:
475.10	Amend
475.12	Amend
475.20	Amend
475.25	Amend

4) Statutory Authority: Implementing and authorized by Section 2310-90 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-90].

5) A Complete Description of the Subjects and Issues Involved: The Department of Public Health laboratories provide testing to support the Department's programs. The Department's laboratories provide these same tests to public health clinics or community based organizations if funding can be obtained and if the surveillance data that would be created is of value to the Department's programs. The use of the Department's laboratories for testing is voluntary.

The amendments revise all tests by name and each test's associated fee. The amendments provide for charging fees based on current calculations of costs, including commodity costs, personnel and benefits, building expenses, equipment maintenance and replacement, quality assurance support, information technology applications, and indirect costs. This change will allow the laboratory to collect reimbursement based on current costs, which change with commodity and operating costs. It will allow the laboratory to obtain Medicaid reimbursement at current operating costs.

The proposed amendments establish a fee to recover costs associated with providing patients their laboratory test results as required by federal legislation.

The proposed amendments update information about the acceptability of samples and specimens, the period of time for which they will be retained, and the ability to share those specimens for quality assurance and method development purposes.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? Yes

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand any State mandates on units of local government.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Written or e-mail comments may be submitted within 45 days after this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761

(217) 782-2043
e-mail: dph.rules@illinois.gov

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected: Local Health Departments and Clinics of Community Based Organizations

B) Reporting, bookkeeping or other procedures required for compliance: No additional bookkeeping will be required.

B) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized: January 2012

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

The full text of the Proposed Amendments begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER d: LABORATORIES AND BLOOD BANKS

PART 475
LABORATORY SERVICE FEES

Section

AUTHORITY: Implementing and authorized by Section 2310-90 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-90]; the Clinical Laboratory Improvement Amendments (42 USC 263a); and the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191).

SOURCE: Adopted and codified at 7 Ill. Reg. 1988, effective January 27, 1983; emergency amendment at 18 Ill. Reg. 15887, effective October 12, 1994, for a maximum of 150 days; emergency expired on March 10, 1995; amended at 20 Ill. Reg. 6958, effective May 5, 1996; amended at 37 Ill. Reg. 6784, effective May 6, 2013; amended at 38 Ill. Reg. _____, effective _____.

Section 475.10 Definitions

"Clinical Laboratory Improvement Amendments" or "CLIA" means federal regulations (Centers for Medicare and Medicaid Services, United States Department of Health and Human Services) providing standards applicable to all facilities or sites in the United States that test human specimens for health assessment or to diagnose, prevent, or treat disease.

"Department" means the Department of Public Health.

"Director" means the Director of the Department of Public Health.

"Laboratory" means the Division of Laboratories of the Illinois Department of Public Health, including its Chicago, Springfield and Carbondale Laboratories, and any other site designated by contract to perform Department Laboratory services.

"Person" means:

the State, its agencies and departments, and its officers and employees;

any local health department and its officers and employees;

any grantee or contractor of the Department that agrees to provide services to the Department, or on behalf of the Department, and officers and employees of a grantee or contractor.

"Quality Control" means a procedure or set of procedures to assure the accuracy of results reported by the laboratory.

"Supplemental Test" means any test approved by the United States Food and Drug Administration or validated under a laboratory's CLIA certification that is used to further characterize a specimen that had received a positive result when initially screened by the laboratory.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 475.12 Referenced Materials

a) The following Illinois statutes and administrative rules are referenced in this Part:

1)~~a)~~ Civil Administrative Code of Illinois [20 ILCS 2310]

2)~~b)~~ Newborn Metabolic Screening and Treatment Code (77 Ill. Adm. Code 661)

3)~~c)~~ Lead Poisoning Prevention Code (77 Ill. Adm. Code 845)

4)~~d)~~ Control of Communicable Diseases Code (77 Ill. Adm. Code 690)

5)~~e)~~ Control of Tuberculosis Code (77 Ill. Adm. Code 696)

b) The following federal statutes are referenced in this Part:

Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)

c) The following federal regulations are incorporated by reference in this Part:

45 CFR 164.524: HIPAA Privacy Rules: Access of Individuals to Protected Health Information (2014)

d) All incorporations by reference of federal regulations refer to the regulations or guidelines on the date specified and do not include any amendments or editions subsequent to the date specified.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 475.20 Submission of Samples or Specimens

Each sample or specimen submitted to the Laboratory for any analysis shall be delivered or shipped in a container and manner to preserve the sample/specimen from contamination or destruction and to allow it to reach the Laboratory in a condition that permits a reliable laboratory analysis.

a) The person submitting the sample/specimen shall deliver it to the Laboratory or send it in a package approved by the U.S. Postal Service or another commercial carrier for shipping. Any sample/specimen that is submitted in a package that violates the U.S. Postal Service's guidelines (or another commercial carrier's guidelines if an alternative carrier is used), is damaged in transit, is not received within the prescribed time frame for analysis, or is otherwise received in a condition that does not permit a reliable laboratory analysis~~,~~ will be discarded. When this occurs, the laboratory result will be reported as indeterminate or unsatisfactory, and the submitter will be notified so that another sample/specimen can be collected and submitted for analysis.

b) For those laboratory services offered, the Laboratory will provide, upon request, sample/specimen collection materials or devices and mailing containers that meet the U.S. Postal Service regulations.

c) Prior to delivering or shipping any sample/specimen to the Laboratory, the person submitting the sample/specimen shall confirm with the Laboratory the availability of the desired laboratory service/analysis and identify which Laboratory site or sites (e.g., Chicago, Springfield, Carbondale or a contract laboratory site) will perform the desired service/analysis and any testing authorization procedures that are required. Samples/specimens shall be delivered or sent only to a specific Laboratory site designated as performing the requested laboratory service or to an alternative site agreed to in advance. Authorization to obtain testing services is based on criteria including, but not limited to: the need for public health surveillance data with consideration of private testing availability; the need to characterize or identify an outbreak; prior approval from the Department or a Local Health Department, or a submission that is required by the Control of Communicable Diseases Code or the Control of Tuberculosis Code. Samples or specimens submitted to the Laboratory without proper authorization will not be tested. Laboratory staff will contact the submitter and determine whether the sample/specimen will be returned or destroyed.

d) The person submitting the sample/specimen shall pay for the postage or transport fee of the package unless alternative arrangements are made with the Laboratory in advance of mailing or shipping a sample/specimen to the Laboratory.

e) Clinical specimens received by the Department will be retained for a minimum of one month. If all test results obtained from a specimen are determined to be within normal range, the specimen will be retained for a maximum of four months. If any test result obtained from a specimen is determined to be abnormal (i.e., out of normal range), the specimen may be retained for a maximum of six years. Specimens that the Department retains may be used within the Department for quality control purposes as required under the Clinical Laboratory Improvement Amendments (CLIA). Based on the Department's testing capabilities, specimens with an abnormal result may be referred to other clinical laboratories for supplemental testing to further characterize the abnormality. After the maximum time period for retention, the Department will destroy all specimens.

f) Cultures, isolates and extracts of pathogens that are provided to the Department or result from testing samples/specimens that have been provided to the Department may be shared by the Department with other public health entities for quality assurance or method development purposes, provided that any and all patient identifiable information has been removed.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 475.25 Fee Schedule

The Department has established fees for those diagnostic Laboratory services listed in subsection (b) ~~of this Section~~.

a) The Laboratory's service fees, itemized in subsection (b) ~~of this Section~~, shall not exceed the Department's actual costs to provide the Laboratory's services, and shall consider the current fees charged by private laboratories for comparable services. The Department's actual costs to perform the Laboratory's services shall include the costs of Laboratory personnel, materials and equipment; the Laboratory's data processing, quality control and support costs (e.g., facility-related costs, postage, telephones, supervision, etc.); any Laboratory marketing sales cost; and other Department costs outside the Laboratory but necessary to support the Laboratory's services (e.g., personnel and financial management costs). The Laboratory's actual costs per unit of service are integrally dependent upon the current technology used to perform laboratory analyses, the test volumes for each laboratory service, and the unit cost of the materials or chemicals/reagents. Because these actual costs per unit of service are subject to change, every effort will be made to review and update the Laboratory's fees on a regular (e.g., biennial) basis.

b) Fees

Unless the sample/specimen is submitted as part of an agreed upon Department surveillance program, in which case the fee may be reduced, the fees for tests are: ~~Each person who submits to the Laboratory any sample or specimen for any of the following laboratory analyses shall pay the indicated fee:~~

Arbovirus Testing	
St. Louis Encephalitis, West Nile Virus,	$73.31

California Encephalitis (Enzyme Immunoassay)	
St. Louis Encephalitis, West Nile Virus, California Encephalitis (supplemental test)	$100.22
Dengue Virus (Enzyme Immunoassay)	$73.31
Dairy Testing	
Aflatoxin, Raw Milk	$214.31
Inhibitor (Beta-lactam)	$65.16
Petrifilm Aerobic Count	$134.81
Phosphatase	$64.66
Container Rinse Test	$74.60
Dairy Salmonella Test	$265.51
Total Coliform	$134.81
Dairy Water, Contained (Coliform)	$78.66
Dairy Water Well/Plant (Coliform)	$26.16
Food Testing	
E. coli O157:H7	$355.12
Listeria monocytogenes	$261.11
Salmonella	$265.51
Shigella	$281.34
Total coliform	$134.81
Enteric Testing	
Salmonella (Amplified Test)	$306.87
Salmonella (Serology)	$239.80
Shigella, E coli, Vibrio and Yersinia (Serology)	$239.80
Shigatoxin 1,2 (Amplified Test)	$86.70
Enteric PFGE (Pulse Field Gel Electrophoresis)	$342.33
Norovirus (Amplified Test)	$86.70
Lead Testing	
Blood lead	$26.33
Environmental lead	$49.79
Parasite Testing	
Malaria (Microscopic Observation)	$82.38

Malaria (Amplified Test)	$157.72
Cryptosporidium (Enzyme Immunoassay)	$78.01
Giardia (Enzyme Immunoassay)	$78.01
Cyclospora (Enzyme Immunoassay)	$78.01
Rabies Testing	
Rabies	$232.78
Sexually Transmitted Infection Testing	
Chlamydia trachomatis (Amplified Test)	$53.77
Neisseria gonorrhea (Amplified Test)	$53.77
Syphilis Serology (Enzyme Immunoassay)	$27.86
Syphilis Serology (Rapid Plasma Reagin)	$14.92
Syphilis Serology (Fluorescent treponemal antibody)	$39.54
HIV Serology 4th Generation (chemiluminescent microparticle immunoassay)	$32.19
HIV Serology Differentiation (Enzyme Immunoassay)	$33.24
HIV Serology Supplemental (Amplified Test)	$86.70
HIV Oral Fluid (Western Blot)	$99.88
Herpes Simplex 1 & 2 (Amplified Test)	$86.70
Tuberculosis (TB) Testing	
TB Acid Fast Bacillus, Smear	$33.14
TB (Culture)	$47.59
TB Drug Resistance	$114.81
TB (Amplified Test)	$142.72
Vaccine Preventable Disease Testing	
Measles (Amplified Test)	$86.70
Mumps (Amplified Test)	$86.70
Pertussis (Amplified Test)	$86.70
Respiratory Virus Panel (Amplified Test)	$86.70
Water Testing	
Bathing Beach E. coli (Microbiology)	$24.12
Private Water Well (Microbiology, Most probable number)	$26.16
Non-Community Public Water Supply	$24.22

(Microbiology, Presence/Absence)
Nitrate-Nitrite (as Nitrogen) $47.41

~~1)~~ ~~Except as provided in subsections (b)(1)(A) and (B) of this Section (in which case the service is free), the fees for the analysis of drinking water are:~~

~~For the detection of total coliforms and Escherichia coli (presence/absence), by a Chromogenic Substrate Coliform Test, following "Standard Methods for the Examination of Water and Wastewater, 22nd 19th Edition", published by the American Public Health Association, American Water Works Association, and Water Environment Federation, 1015 Fifteenth Street, Washington, D.C. 20005 (20121995)~~ ~~$7.00 per sample~~

~~For the detection of nitrate/nitrite levels, by USEPA Method 353.2, published by Environmental Monitoring Systems Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (August 1993)~~ ~~$6.00 per sample~~

~~For the combined detection of coliform and nitrates/nitrites, the methods cited in this subsection (b)(1)~~ ~~$12.00 per sample~~

~~A)~~ ~~unless the sample is submitted for a non-community public water supply; or~~

~~B)~~ ~~unless the sample is submitted by a local health department that has entered into a potable water program agreement with the Department or submitted by a Department employee on behalf of a resident of a jurisdiction without any local health department, and under at least one of the following circumstances:~~

~~i)~~ ~~for a new water well that has been inspected by the local~~

health department or Department employee;

ii) for a water well serving an infant under six months of age; or

iii) in support of an investigation of a suspected waterborne illness.

2) For samples submitted by a public or private Illinois school served by an active non-transient non-community public water supply the services shall be free of charge. For samples submitted by any other entity served by an active non-transient non-community public water supply that serves a population of fewer than 100 individuals the fees for the chemical analysis of drinking water for the following contaminants are:

Inorganics (Metals), by USEPA Method 200.9, following "Methods for the Determination of Metals in Environmental Samples – Supplement I", EPA-600/R-94-111, published by Environmental Monitoring Systems Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (May 1994)	
Cadmium	$6.00 per sample
Chromium	$6.00 per sample
Copper	$5.50 per sample
Lead	$5.50 per sample
Herbicides, by USEPA Method 515.1, following "Methods for the Determination of Organic Compounds in Drinking Water", EPA-600/4-88-039, published by Environmental Monitoring Systems Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (July 1991)	$117.00 per sample
Pesticides (chlorinated hydrocarbons and organophosphates), by USEPA Method 508, following "Methods for the Determination of Organic Compounds in Drinking Water", EPA-	$81.00 per sample

~~600/4-88-039, published by Environmental Monitoring Systems Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (July 1991)~~

~~Volatile Organic Compounds, by USEPA Method 524.2, following "Methods for the Determination of Organic Compounds in Drinking Water – Supplement II", EPA-600/R-92-129, published by Environmental Monitoring Systems Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (August 1992)~~ ~~$146.00 per sample~~

~~For laboratory services specified in this subsection, the Department will only accept samples from entities served by an active non-transient non-community public water supply that serves a population of fewer than 100 individuals, except for public or private Illinois school.~~

~~3)~~ ~~Unless the specimen is submitted by a Department-funded HIV counseling and testing site or unless such analysis is requested as part of an HIV seroprevalence study that is funded or approved by the Department (in which case the service is free), the fees for analyses of a blood specimen are:~~

~~For the presence of Human Immunodeficiency Virus (HIV) antibodies, using an enzyme-linked immunosorbent assay (ELISA) test with confirmatory Western blot test (if necessary)~~ ~~$8.00 per specimen~~

~~For the enumeration of CD4 lymphocytes using flow cytometry technology~~ ~~$91.00 per specimen~~

~~4)~~ ~~Unless the sample/specimen is submitted by a health care provider (including local health departments clinics) designated annually by the Department's Division of Infectious Diseases as serving a population with a high incidence of sexually-transmitted diseases and exempt from the following laboratory fees (in which case the service is free), the fees for~~

~~analysis for the presence of~~ the following ~~sexually transmitted diseases are:~~

~~Chlamydia trachomatis and Neisseria gonorrhea, same swab (GenProbe)~~	~~$12.50 per specimen~~
~~Syphilis serology (RPR and FTA)~~	~~$6.50 per specimen~~

~~5)~~ ~~Except for samples/specimens submitted by the Chicago Department of Public Health (in which case the service is free), the fee for pap smear analysis (cytology) shall be:~~ ~~$11.50 per specimen~~

~~6)~~ ~~The fees for the following services are:~~

~~Hydrocarbons (volatile and extractable) for drinking water, by USEPA SW846 Method 8000A, following "Test Methods for Evaluating Solid Waste – Physical/Chemical Methods (SW846), Revised Update II", published by Environmental Monitoring Systems Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (September 1994)~~	~~$349.00 per sample~~
~~Prenatal screening panel, which includes testing for Hepatitis, HIV, Rubella and Syphilis~~	~~$31.00 per patient~~
~~Alpha-fetoprotein screening~~	~~$21.00 per specimen~~

c) Results of clinical laboratory tests will be provided to medical providers that submit a patient specimen. A duplicate copy of a patient's test result will be provided upon written request by the medical provider that originally ordered the test. Other medical providers will be provided a copy of patient test results upon the Department's receipt of proof of the patient's consent to release the patient's test result to that medical provider.

d) In accordance with the HIPAA Privacy Rules, upon receipt of a written notarized request by a patient or a patient's legal representative, the Department will provide a copy of the patient's clinical test result to the patient, patient's legal

representative or persons designated by the patient or the patient's legal representative. The request shall identify the patient, the patient's date of birth, and the test performed. The request shall be accompanied by a payment of $25.

~~c)~~e) The Director may reduce any of the fees listed in subsection (b) ~~of this Section,~~ pursuant to a written agreement, executed prior to submission of the sample/specimen, between the Department and the person to be submitting the sample/specimen. Examples of instances when reduced service fees may be considered include, but are not limited to, when the samples/specimens from, or test volumes for, one submitter will be very large; when a large one-time advance payment for all services is desired; and where the Department is participating in a special study requiring laboratory analysis.

~~d)~~f) The Director may waive any of the standard laboratory fees prescribed in subsection (b) ~~of this Section~~ when the sample/specimen is submitted by Department staff (to support Department programs or services), another State agency, or any unit of local government, provided that the fee waiver is requested in writing and approved by the Director in writing prior to submission of the sample/specimen.

~~e)~~g) The Director may enter into a written agreement with any governmental unit (contained within the definition of person) to provide additional laboratory services beyond those listed in this Part. The ~~Such~~ agreement will ~~shall~~ specify any conditions established for the submission of samples/specimens and the fees for the ~~such~~ services.

(Source: Amended at 38 Ill. Reg. _____, effective _____)