

ILLINOIS REGISTER

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)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
475.10	Amend
475.12	New
475.20	Amend
475.25	Amend
475.30	Amend
475.50	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 and edits delete all tests by name and each test's associated fee. The amendments and edits provide for charging fees based on current calculations of costs, including commodity costs, personnel and fringe 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 update the fee for returned checks or insufficient payment to cover processing costs.

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*.

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- 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? No
- 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

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

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

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

PART 475
LABORATORY SERVICE FEES

Section	
475.10	Definitions
<u>475.12</u>	<u>Referenced Materials</u>
475.15	Applicability
475.20	Submission of Samples or Specimens
475.25	Fee Schedule
475.30	Statement of Fee Assessment
475.40	Payment of Fees
475.50	Failure <u>to Submit</u> of Payment

AUTHORITY: Implementing and authorized by Section 2310-90 55.09 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-9055.09].

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. _____, effective _____.

Section 475.10 Definitions

~~As used in this Part, the terms specified below shall have the meanings ascribed to them in this Part.~~

"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.

~~"Non-Community Public Water Supply" means a public water system that which~~

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~~is not a community water system, and has at least 15 service connections used by nonresidents, or regularly serves 25 or more nonresident individuals daily for at least 60 days per year. Water vending machines are considered non-community public water supplies.~~

~~"Non-Transient Non-Community Public Water Supply" means a non-community public water supply that regularly serves the same 25 or more persons at least 6 months per year.~~

"Person" means:

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

any local health department ~~or school district~~, and its officers and employees thereof;

~~any entity served by a non-community public water supply, and its officers and employees thereof;~~

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 ~~such~~ a grantee or contractor.

(Source: Amended at 37 Ill. Reg. _____, effective _____)

Section 475.12 Referenced Materials

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

- a) Civil Administrative Code of Illinois [20 ILCS 2310]
- b) Newborn Metabolic Screening and Treatment Code (77 Ill. Adm. Code 661)
- c) Lead Poisoning Prevention Code (77 Ill. Adm. Code 845)

(Source: Added at 37 Ill. Reg. _____, effective _____)

Section 475.15 Applicability

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- a) This Part is applicable only to diagnostic laboratory tests ~~listed in Section 475.25, (Fee Schedule)~~. This Part does not apply to reference laboratory tests performed free of charge ~~free of charge~~ by the Department, or to other laboratory analyses ~~historically performed~~ free of charge ~~free of charge~~ for either the Department or local health departments.
- b) This Part is not applicable to the Department's laboratory screening of newborns for metabolic diseases under the "Newborn Metabolic Screening and Treatment Code" (~~77 Ill. Adm. Code 661~~) or to screening of children for elevated blood lead levels under the "Lead Poisoning Prevention Code" (~~77 Ill. Adm. Code 845~~). The fees established in this Part are in addition to other laboratory fees established under separate statutory authority for two specific purposes: screening newborns for metabolic diseases under the "Newborn Metabolic Screening and Treatment Code" (~~77 Ill. Adm. Code 661~~); and screening children for elevated blood lead levels under the "Lead Poisoning Prevention Code" (~~77 Ill. Adm. Code 845~~).

(Source: Amended at 37 Ill. Reg. _____, effective _____)

Section 475.20 Submission of Samples or Specimens

Each sample or specimen submitted to the Laboratory for any analysis shall ~~must~~ 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~~ It is the responsibility of the person submitting the sample/specimen shall ~~to~~ deliver it to the Laboratory or ~~to~~ send it in a package approved by the U.S. Postal Service, or another commercial carrier ~~to be used~~, for ~~such~~ 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 ~~indeterminant~~ 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 ~~shall~~ provide, upon request, sample/specimen collection materials or devices and mailing containers that meet the U.S. Postal Service regulations.

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- c) ~~Prior to delivering or shipping any sample/specimen to the Laboratory, it is the responsibility of the person submitting the sample/specimen~~ shall to confirm with the Laboratory the availability of the desired laboratory service/analysis and; to identify which Laboratory site or sites site(s) (e.g., Chicago, Springfield, Carbondale or a contract Laboratory laboratory site) will perform the desired service/analysis; and to determine to which site the sample/specimen should be submitted. ~~Samples~~ Sample/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.
- d) ~~The~~ It is the responsibility of the person submitting the sample/specimen shall to 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.

(Source: Amended at 37 Ill. Reg. _____, effective _____)

Section 475.25 Fee Schedule

The Department will establish ~~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,~~ will shall not exceed the Department's actual costs to provide the Laboratory's services, and will shall consider the current fees charged by private laboratories, including Medicaid reimbursement rates, for comparable services. The Department's actual costs to perform the Laboratory's services and for reimbursement by Medicaid will 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) ~~Each person who submits to the Laboratory any sample or specimen for any of the following laboratory analyses shall pay the indicated fee:~~

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- 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, 19th Edition", published by the American Public Health Association, American Water Works Association, and Water Environment Federation, 1015 Fifteenth Street, Washington, D.C. 20005 (1995)~~ ~~-\$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 a Department employee;~~
 - ~~ii) for a water well serving an infant under six months of age;~~
- ~~or~~

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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 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)~~

~~\$81.00 per sample~~

~~Volatile Organic Compounds, by USEPA Method~~

~~\$146.00 per sample~~

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~~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)~~

~~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 the 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) enzyme immunoassay (EIA) test with confirmatory Western blot test (if necessary) \$8.00 per specimen~~

~~For a 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 department 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 gonorrhoea, same swab (GenProbe) \$12.50 per specimen~~

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| | 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 |
- b)e) The Director may reduce any established fee ~~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 ~~when~~ where the Department is participating in a special study requiring laboratory analysis.
- c)d) 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) The Director may enter into a written agreement with any governmental unit

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(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 37 Ill. Reg. _____, effective _____)

Section 475.30 Statement of Fee Assessment

- a) Fees for laboratory analyses shall be paid prior to services being provided, unless prior arrangements are made with the Department to bill the person submitting the sample/specimen.
- b) For persons with approval from the Department to submit samples/specimens without advance or accompanying payment, statements of fee assessment will ~~shall~~ be mailed or otherwise delivered to persons submitting samples for analysis monthly or quarterly as determined by the Director, depending on the number of samples or other circumstances unique to the testing.
- c) Receipt of statements of fee assessment will ~~shall~~ be presumed.

(Source: Amended at 37 Ill. Reg. _____, effective _____)

Section 475.50 Failure to Submit of Payment

- a) Unless prior arrangements have been made with the Department to bill the submitter for laboratory services rendered, the Laboratory may refuse to accept or may discard any sample/specimen that is not accompanied by the required service fee.
- b) For local health departments and other persons approved to submit samples/specimens without advance or accompanying payment, failure to submit ~~of~~ full payment within two months after ~~of~~ assessment shall be grounds for the Department to refuse future samples/specimens.
- c) The fee for a dishonored negotiable instrument, including, but not limited to, returned checks or insufficient payment, will ~~shall~~ be \$35.00 ~~\$10.00~~.

(Source: Amended at 37 Ill. Reg. _____, effective _____)