

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

- 1) Heading of the Part: Laboratory Service Fees
- 2) Code Citation: 77 Ill. Adm. Code 475
- 3)

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| <u>Section Number:</u> | <u>Proposed Action:</u> |
| 475.25 | Amendment |
- 4) Statutory Authority: 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).
- 5) A Complete Description of the Subjects and Issues Involved: The proposed rulemaking amends language to allow the Department to contract with commercial laboratories and governmental laboratories for the provision of additional laboratory services.

The economic effect on 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 three 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? 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: Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

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- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: None
 - B) Reporting, bookkeeping or other procedures required for compliance: None
 - C) Types of professional skills necessary for compliance: CLIA licensed laboratory
- 14) Regulatory Agenda on which this rulemaking was summarized: This rule was not included on either of the two most recent Regulatory Agendas because the need for the rulemaking was not apparent when the Regulatory Agendas were prepared.

The full text of the Proposed Amendment 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 |
| 475.12 | Referenced Materials |
| 475.15 | Applicability |
| 475.17 | Authorization to Submit Specimens or Samples |
| 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 to Submit Payment |

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. 21494, effective October 31, 2014; amended at 40 Ill. Reg. _____, effective _____.

Section 475.25 Fee Schedule

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

- a) The Laboratory's service fees, itemized in subsection (b), 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,

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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 or specimen~~~~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:

Arbovirus Testing

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| St. Louis Encephalitis, West Nile Virus, California Encephalitis (Enzyme Immunoassay) | \$73.31 |
| St. Louis Encephalitis, West Nile Virus, California Encephalitis (Supplemental Test) | \$100.22 |
| Dengue Virus (Enzyme Immunoassay) | \$73.31 |

Dairy Testing

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|-----------------------------------|----------|
| 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

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|------------------------|----------|
| E. coli O157:H7 | \$355.12 |
| Listeria monocytogenes | \$261.11 |
| Salmonella | \$265.51 |
| Shigella | \$281.34 |
| Total coliform | \$134.81 |

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Enteric Testing

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| 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

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|--------------------|---------|
| Blood Lead | \$26.33 |
| Environmental Lead | \$49.79 |

Parasite Testing

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| 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

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| Rabies | \$232.78 |
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Sexually Transmitted Infection Testing

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| 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 4 th 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

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| TB Acid Fast Bacillus, Smear | \$33.14 |
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| TB (Culture) | \$47.59 |
| TB Drug Resistance | \$114.81 |
| TB (Amplified Test) | \$142.72 |

Vaccine Preventable Disease Testing

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|--|---------|
| Measles (Amplified Test) | \$86.70 |
| Mumps (Amplified Test) | \$86.70 |
| Pertussis (Amplified Test) | \$86.70 |
| Respiratory Virus Panel (Amplified Test) | \$86.70 |

Water Testing

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| Bathing Beach E. coli (Microbiology) | \$24.12 |
| Private Water Well (Microbiology, Most Probable Number) | \$26.16 |
| Non-Community Public Water Supply (Microbiology, Presence/Absence) | \$24.22 |
| Nitrate-Nitrite (as Nitrogen) | \$47.41 |

- 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.
- e) The Director may reduce any of the fees listed in subsection (b), pursuant to a written agreement, executed prior to submission of the ~~sample or specimen~~sample or specimen, between the Department and the person to be submitting the ~~sample or specimen~~sample or specimen. Examples of instances when reduced service fees may be considered include, but are not limited to, when the ~~samples or specimens~~samples or 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.

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- f) The Director may waive any of the standard ~~laboratory~~laboratory fees prescribed in subsection (b) when the ~~sample or specimens~~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.
- g) The Director may enter into a written agreement with any commercial laboratory or governmental unit (contained within the definition of person) to provide additional laboratory services ~~beyond those listed in this Part~~. The agreement will specify any conditions established for the submission of samples or specimens~~samples/specimens~~ and the fees for the services.

(Source: Amended at 40 Ill. Reg. _____, effective _____)