(Statutory authority: Public Health Law, Section 576(4))

Sec.

58-3.1 Definitions
58-3.2 Laboratory inspection and reference fee
58-3.3 Reporting
58-3.4 Quarterly payments
58-3.5 Suspension or nonrenewal of laboratory permit
58-3.6 Fees
58-3.7 Gross annual receipts
58-3.8 Out-of-state laboratory seeking permit
58-3.9 Effective dates

Section 58-3.1 Definitions.

(a) Gross annual receipts for clinical laboratories able to segregate income. For independent laboratories or laboratories operated within facilities which can segregate their laboratory income from total facility income, gross annual receipts shall mean the total income of the laboratory from all sources for all clinical laboratory tests performed pursuant to its permit, less any amounts paid to reference laboratories for such tests which are referred.

(b) Gross annual receipts for clinical laboratories unable to segregate laboratory income.

(1) For laboratories operated by health maintenance organizations, facilities with operating certificates issued pursuant to section 2805 of the Public Health Law, and other similar facilities which are reimbursed by third-party payors for laboratory services as part of an all inclusive facility per diem rate and which cannot segregate laboratory income from total facility income, gross annual receipts shall mean the amount computed by multiplying the total annual cost of the laboratory, by a fraction, the numerator of which is the gross revenue of the facility and the denominator of which is the gross cost of operating the facility. This amount must be further adjusted by subtracting any amounts paid to reference laboratories for such tests which are referred. Laboratories must obtain prior department approval to use this method by documenting that they are unable to segregate income.

(2) For all other clinical laboratories unable to segregate their annual income from tests performed pursuant to their New York State permit, gross annual receipts shall mean the amount the laboratory would have received had it billed the prevailing rate for these services. The prevailing rate shall mean the fee
schedule for clinical laboratory services as listed on pages 5-1 through 5-14 of the Medicaid Management Information System Provider Manual for Laboratories, March 1982 edition, as published by the New York State Department of Social Services. Copies of this publication are available from the Department of Social Services, 40 North Pearl Street, Albany, NY 12243, and a copy is available for inspection and copying from the records access officer of the Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. Laboratories must obtain prior department approval to use this method by documenting that they are unable to identify laboratory income.

(c) Inspection and reference fee shall mean the fee charged to a clinical laboratory calculated by multiplying the total operating expenses of the clinical laboratory evaluation program of the Department of Health by a fraction, the numerator of which is the gross annual receipts of such laboratory and the denominator of which is the total gross annual receipts of all laboratories issued permits.

(d) Permit year shall mean July 1st to June 30th.

58-3.2 Laboratory inspection and reference fee.

Each laboratory issued a permit by the department pursuant to section 575 of the Public Health Law shall be charged an annual laboratory inspection and reference fee.

58-3.3 Reporting.

(a) On or before May 1st of each State fiscal year (April 1st to March 31st), the department will advise each laboratory of the total estimated cost of the clinical laboratory improvement program for the previous State fiscal year.

(b) On or before May 15th, each laboratory will certify and report its gross annual receipts for the previous calendar year on forms to be provided by the department. If requested by the laboratory, this report shall be deemed confidential and exempt from disclosure under the Freedom of Information Law (article 6 of the Public Officers Law), pursuant to the authority in section 89(5) of the Public Officers Law. Knowing and/or willful failure to report or inaccurate reporting shall result in nonrenewal of the laboratory permit.

(c) On or before June 1st, the department shall bill each laboratory for its inspection and reference fee and shall advise each laboratory of the total gross receipts reported by all laboratories.

58-3.4 Quarterly payments.
At least quarterly payments must be made. If the laboratory elects to make quarterly payments, equal quarterly payments must be made by June 30th, September 30th, December 31st and March 10th of the State fiscal year to which the billing relates. Nothing herein precludes full payment from being made before these dates.

58-3.5 Suspension or nonrenewal of laboratory permit.

Knowing and/or willful failure to meet the quarterly payment requirement will result in suspension or nonrenewal of the laboratory permit.

58-3.6 Fees.

On or before September 15th, the department will review the annual cost of the clinical laboratory inspection program as initially estimated. Fees will be adjusted when any change results in an increase or decrease in fees of more than $100 per laboratory. If an adjustment is required, the department shall notify the laboratories of any additional fees or credits by October 15th. Any additional fees are payable not later than 30 days after the date of the notification statement. Credits shall be applied to the next regular payment.

58-3.7 Gross annual receipts.

(a) A laboratory which has no gross annual receipts because it did not operate in New York State the previous permit year shall pay a first year accreditation fee of $1,000 regardless of the number of months remaining in the permit year. When applying for renewal of that permit, the laboratory shall report its gross receipts for the calendar months in which it operated and these receipts shall be projected to a 12-month basis for the purpose of computing gross annual receipts.

(b) A laboratory which has no permit, but accepted business which required it to have a New York State permit, had gross annual receipts in the previous permit year, and applies for a permit after commencement of the permit year shall pay a fee computed as an annual fee but prorated for the months remaining in the permit year, or $1,000, whichever is greater.

58-3.8 Out-of-state laboratory seeking permit.

(a) Prior to any onsite inspection, an out-of-state laboratory possessing or seeking a New York State permit shall pay to the department, by certified check, bank check, teller's check or money order, a fee calculated by the department and consisting of the following components:
(1) a transportation expense, which shall be either the actual travel expense if travel is by common carrier, or a mileage expense at the rate negotiated between the State and the union representing the employees scheduled to conduct the inspection; and

(2) a per diem expense as specified by the New York State Comptroller for the inspecting employees, multiplied by the number of additional days estimated by the department to be necessary for travel and the actual inspection.

(b) In calculating this fee, the department shall estimate the total cost of the components specified in paragraph (a)(1) of this section and divide it equally among the laboratories inspected on any trip.

(c) In the event the department underestimates any of the above expenses, the laboratory shall pay any difference between the estimate and the actual expense.

(d) Fees collected shall be credited to the Clinical Laboratory Reference Fee Account. In the event the department overestimates any of the above expenses, the laboratory shall be notified of the difference between the estimate and the actual expense, and its account shall be credited that amount unless a refund is requested.

(e) Failure to pay the fee for out-of-state inspection will result in suspension or nonrenewal of the laboratory permit.

58-3.9 Effective dates.

(a) Until March 31, 1986, the following dates shall have the following meanings:
(1) In section 58-3.3(a), May 1st shall mean the effective date of this regulation.

(2) In section 58-3.3(b), May 15th shall mean a date 10 days after the effective date of this regulation.

(3) In section 58-3.3(c), June 1st shall mean a date 45 days after the effective date of this regulation.

(4) In section 58-3.4, June 30th, September 30th, December 31st and March 10th shall mean dates to be negotiated by the department and each laboratory for the payment of quarterly installments of the 1985-86 fee; provided, however, that full payment must be made by March 10, 1986.

(b) The provisions of this section shall expire on March 31, 1986.