

**NEW YORK STATE  
MEDICAID PROGRAM**

**FEE-FOR-SERVICE  
LABORATORY MANUAL  
POLICY GUIDELINES**

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## Section I - Requirements for Participation in Medicaid

The New York State Public Health Law, Section 574, requires that clinical laboratories which solicit specimens obtained in New York State possess a New York State clinical laboratory permit. In accordance with the Health Care Finance Administration (HCFA) Clinical Laboratory Improvement Amendments (CLIA) of 1988 all clinical laboratories must hold a valid CLIA certificate. New York State exempt status with HCFA allows clinical laboratories located within New York State to meet CLIA requirements by holding a New York State clinical laboratory permit.

Laboratory services may be provided to members by any of following:

- Clinical laboratories which have a valid clinical laboratory permit in the appropriate categories from the New York State Department of Health (DOH).
- Clinical laboratories that are part of a hospital or other Article 28 facility (e.g., freestanding diagnostic and treatment center) holding a DOH operating certificate, provided that the laboratory holds a valid clinical laboratory permit in the appropriate categories from the DOH.
- Clinical laboratories operated by City, County, or State government, which hold a valid DOH clinical laboratory permit, and which perform tests for members other than those required by the Commissioner of Health to be performed free of charge or in the public interest, e.g., tests which concern disease detection, are mandated by the State Sanitary Code or are parts of programs supported by DOH or research grants.
- Out-of-State clinical laboratories accepting specimens originating from within New York State and holding a valid New York State clinical laboratory permit. Out-of-state laboratories must have a valid CLIA certificate as well as be currently licensed or certified by the responsible agency in the state where it is located, if the state requires licensing or certification.
- Out-of-State clinical laboratories serving New York State Medicaid members requiring medical care while temporarily absent from the State, if currently licensed or certified by the responsible agency in the state where it is located. Out-of-state laboratories must have a valid CLIA certificate.
- Physicians, nurse practitioners, licensed midwives, or podiatrists (within the scope of their practice), subject to the limitations listed in the New York State Procedure Code Sections and Fee Schedules contained in the **Medicaid Physician Manual**, **Medicaid Nurse Practitioner Manual**, **Medicaid Midwife Manual** or **Medicaid Podiatry Manual**. Practitioners performing laboratory tests must possess the appropriate CLIA certificate.

Questions about the State licensure program, applications, information on specific laboratories, permit status, copies of law and regulation or other assistance can be obtained from:

**Clinical Laboratory Evaluation Program**

Biggs Laboratory

Wadsworth Center

New York State Department of Health

Empire State Plaza

Albany, New York 12237

**518-485-5378**

**email: [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov)**

## Fee-for-Service Provider Enrollment for Laboratory Services

In determining whether to contract with an applicant for participation as a fee-for-service provider in the New York State Medicaid program, the Department of Health Office of Health Insurance Programs in conjunction with the Office of the Medicaid Inspector General, may consider any factor which may affect the effective and efficient administration of the program, including but not limited to the current availability of medical care, services or supplies to recipients (18 NYCRR §504.5(a)(14)). The policy and procedure for determining the current availability of enrolled Medicaid providers for laboratory services is based upon evaluation of the number of active Medicaid laboratory providers, to determine on a case-by-case basis if there is an unmet need for those services pursuant to 18 NYCRR §504.5(a)(14). Unmet need for laboratory services is evaluated based upon the categories of testing and tests provided by the laboratory applicant, and whether there is currently an unmet need identified by the Medicaid program for a specific category of testing, or a specific test(s). Geographic location of the laboratory's physical testing site does not affect the effective and efficient provision of laboratory services in the Medicaid program, because the specimens which are taken from Medicaid enrollees at collection sites are sent directly to laboratory testing sites without requiring the Medicaid enrollee to travel to the physical location of the laboratory's testing facility. This information, together with any information the Medicaid program may have received concerning access to specific categories of testing or specific tests, is evaluated to determine if there already are an adequate number of enrolled providers of laboratory services. If it is determined that the Medicaid program currently has an adequate number of enrolled providers for the categories of testing offered by the applicant, the applicant's enrollment application will be denied; or a limited provider enrollment may be granted only as to a specific test(s) and/or category or categories of testing for which there is an unmet need. Each such determination is made on a case-by-case basis.

## Regulations for Laboratory Services

Regulations governing the delivery of laboratory services to Medicaid members can be found at Title 18 of the New York Code of Rules and Regulations Section 505.7:

<http://www.health.ny.gov/nysdoh/phforum/nycrr18.htm>

## Section II - Laboratory Services

All laboratory examinations, which must be medically necessary and related to the specific needs, complaints, or symptoms of the patient, require the written order of a physician or qualified practitioner. Laboratory examinations initiated by the laboratory based on the findings or test results of a preliminary procedure ("reflex testing") are reimbursable only when ordered in writing by the ordering practitioner.

### Classification of Laboratory Procedures

The Medicaid Program allows a clinical laboratory to bill for appropriately ordered tests which appear in the Fee Schedule of this Manual and which are within the scope of the laboratory's permit, as indicated by the categories for which Health Department approval has been obtained. Laboratories may be restricted to the tests they can perform based on Department approval. Claims received for tests outside of this restriction and/or not on the Fee Schedule will not be reimbursed and cannot be billed to the member.

### Ordering Laboratory Services

A clinical laboratory may examine a specimen only when the test has been ordered by an enrolled licensed physician, an enrolled qualified practitioner or designee and shall consist of either (a) handwritten signature of name or initials, or (b) electronic or computer-generated signature of name or unique identifier acceptable to the Department.

Laboratory test orders must be written on: (1) a qualified practitioner's prescription form, electronic order form, or imprinted stationery, with all tests to be performed listed individually in writing by the practitioner; or (2) a laboratory requisition, either hard copy or electronic, which is issued by a clinical laboratory and which permits the selection of individual tests; or (3) a pre-printed order form which is issued by a hospital or other facility certified under Article 28 of the Public Health Law for services to be provided by the facility's laboratory.

The request by the enrolled provider can be verbal for emergency situations only. However, in this instance, the laboratory is also required by 10 NYCRR Part 58 to obtain a written request from the physician or qualified practitioner. Services not verified by a written order will not be reimbursed by Medicaid.

A laboratory test order must contain all the information required by 10 NYCRR Part 58. Additionally, the following specific information must be provided to the testing laboratory by the referring practitioner or forwarding laboratory for purposes of Medicaid billing:

## Laboratory Manual Policy Guidelines

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### Member Information:

Name  
Medicaid ID Number (CIN)  
Gender  
Medicare Number  
Or Other Insurance Information

### Ordering Practitioner Information:

NPI Number of Medicaid-enrolled provider  
Name  
Diagnosis (ICD-10-CM)  
Address  
Telephone Number  
Services Requested  
Date of Request

### Indication if Service Related to:

Accident  
Crime  
Family Planning  
Abortion or Sterilization  
Physically Handicapped Children's Program

Orders for laboratory tests must indicate the diagnosis, symptomatology, suspected condition or reason for the encounter, either by use of the appropriate ICD-10-CM code or a narrative description. Non-specific coding does not satisfy this requirement.

Physician's assistants may order laboratory services under the direction of a supervising physician. The Medicaid identification number (or license number if not enrolled in Medicaid) of the supervising physician must appear on the order form.

The following policy applies only to Independent Laboratories (Category of Service 1000):

- Members who are restricted to a primary provider (physician, clinic, podiatrist or dentist) are prohibited from obtaining ancillary services when such services are ordered by non-primary providers. When a member is restricted to a primary provider, all laboratory services must be ordered by that provider, or by a provider to whom the member was referred by the primary provider.

## Reference Testing

It is within generally accepted laboratory practices for a laboratory to refer specimens to another laboratory pursuant to the limited conditions outlined in 10 NYCRR Part 58. These regulations can be found on the internet at:

<http://www.health.ny.gov/nysdoh/phforum/nycrr10.htm>

This includes specimens for infrequently performed tests that are not included in the laboratories permit category of those requiring specialized equipment and skills.

Routine acceptance of Medicaid specimens or referral of such specimens to circumvent a laboratory's ineligibility to receive Medicaid reimbursement is not consistent with generally accepted practices for specimen referral and conflicts with program policy.

The following program requirements are applicable to reference testing:

- The forwarding laboratory must ascertain that the testing laboratory holds the appropriate New York State clinical laboratory permit in the appropriate categories to perform the requested tests and participates in the Medicaid Program.
- The forwarding laboratory must provide the testing laboratory with an unaltered copy of the practitioner's original order and all additional information necessary for the testing laboratory to submit a claim to Medicaid.
- The forwarding laboratory must indicate to the testing laboratory those member specific services which are not directly billable to Medicaid because such services are reimbursed as part of a facility's inpatient or clinic rate.

Claim submission for a procedure performed on a specimen referred by another laboratory constitutes acceptance of responsibility by the testing laboratory of adherence to Medicaid Program policy governing all aspects of ordering, testing, and reporting of results.

## Results of Tests

A laboratory is entitled to payment for a laboratory service only if the result of the test has been reported in writing to the licensed physician or the qualified practitioner who requested it. Reports may not be issued to the subject of the test except with the written consent of the physician or qualified practitioner.

## Date of Service Definition

Medicaid defines the date of service for clinical laboratory providers as the date on which the specimen was collected from the ordering practitioner. This also includes the items as follows:

- For specimen collections that span more than one calendar day, the date of service is the date the collection began.
- For laboratory tests that use a specimen taken from storage, the date of service is the date the specimen was removed from storage.

Department rules at 10 NYCRR Subpart 58-.11 require laboratory reports to contain the



date of collection. Laboratories must make every effort to obtain this information from the ordering practitioner or his or her agent (such as a visiting nurse) whenever collection is not performed by laboratory employees.

## Practitioner Designation of Authority to Sign Orders for Laboratory Tests

Regulations allow practitioners to designate to personnel/staff the authority to sign laboratory test order form(s) on their behalf.

- Practitioners and designated staff may use electronic or computer-generated means of authentication.
- The practitioner must still select the appropriate laboratory tests based on his/her assessment of medical necessity.
- Practitioners choosing this option remain financially responsible for laboratory tests ordered on their behalf.

## Practitioner Electronic Laboratory Test Ordering and Signature

Revised regulations permit qualified ordering practitioners to use electronic signatures for laboratory test ordering.

Practitioners and laboratories that use electronic means to order laboratory tests must employ safeguards to ensure the security and confidentiality of all information. These measures shall include but not be limited to:

- The assignment, as appropriate, of a unique identifier assigned in a confidential manner.
- Certification in writing by the practitioner and the practitioner's authorized user that each identifier assigned is confidential and is available and accessible only to the staff authorized to use the electronic or computer authentication system.
- Implementation of policies and procedures to ensure the security of electronic or computer equipment from unwarranted access.

- Implementation of policies and procedures that restrict access to information and data to those individuals who have need and permission for such access.
- Develop a means to track access by users.

Again, the ordering practitioner remains responsible for ordered tests.

### Standing Orders

Qualified practitioners may authorize certain laboratory tests to be performed at defined intervals over a period of six months with one “standing order” in certain clinical situations as follows:

- CBC and platelet count for cancer treatment members;
- Blood glucose testing for diabetics;
- Prothrombin and digoxin levels for cardiac members; and
- Monitoring therapeutic levels of prescribed drugs.

For all other tests and clinical situations, a separate order is required for each date that testing is requested.

### Laboratory Tests Must Be Ordered Individually

Medicaid reimbursement to an independent clinical laboratory will only be made for laboratory tests ordered individually. For purposes of this ordering requirement, a panel defined by a single procedure code in the Medicaid Laboratory Procedure Code Manual is considered to be an individual test. No payment will be made to a clinical laboratory for tests ordered as groupings or combinations of tests. Note: Organ or disease-oriented panels identified in Rule 11 in the Laboratory Procedure Code Section may be ordered as a panel.

### Laboratory Service Provided in A Member’s Home

Laboratories are eligible for Medicaid reimbursement for travel expenses associated with in-home phlebotomy services, i.e., blood draws, provided under circumstances outlined below.

Ordered testing and its scheduling must be medically necessary, and the member must be eligible for in-home phlebotomy as documented by a medical practitioner and defined

below. This must be specified by the ordering practitioner on the laboratory requisition or on other documentation retained by the laboratory.

**A member is eligible for in-home phlebotomy if:**

- the member is homebound, which means he or she has a condition due to illness or injury that precludes access to routine medical services outside of his/her residence without special arrangements for transportation, i.e., ambulance, ambulette, and taxi with assistance in areas where public transportation is unavailable; or has a condition that makes leaving the residence medically contraindicated; **and**,
- the member is participating in a Medicaid-covered home care program or is currently receiving a Medicaid-covered home care service, i.e., personal care services, certified home health agency (CHHA) services, consumer-directed personal assistance services, and the Long Term Home Health Care Program (LTHHCP).

**Travel expenses are NOT a covered service if they are solely to:**

- draw blood from a member who receives medical services in his or her residence from a professional whose scope of practice authorizes the drawing of blood; or,
- pick-up and transport a specimen collected by a home health care provider or anyone other than a laboratory representative.

**Laboratories may claim reimbursement for in-home phlebotomy travel expenses:**

- Travel expenses should be claimed using code P9604.
- Maximum reimbursement is \$9.35 one way, \$18.70 round-trip, regardless of distance.
- The laboratory is entitled to only one fee for one-way or round-trip travel to a single address, regardless of the number of specimens collected or the number of members drawn at that location.
- The number of specimens collected per trip must be documented.
- To calculate the appropriate reimbursement amount for claiming travel to and from in-home phlebotomy services, multiply the number of trips or stops (including the return trip to the laboratory) by \$9.35 and divide this amount by the number of members seen.

- The laboratory will prorate when the claim is submitted based on the number of members seen on that trip.
- The “single address” is defined as a building or complex with the same entrance and egress off of a public road, such as an apartment complex.

**Rules for billing, including prorating for multiple members:**

1. **One member at one site:** A laboratory representative travels from the laboratory to the home of one member and returns to the laboratory without making any other stops. The trip out and back is paid as a round-trip. The laboratory should submit a single line claim for \$18.70 ( $2 \times \$9.35 = \$18.70$ ).
2. **One member at each of multiple sites:** A laboratory representative travels in a circuit from the laboratory to the home of each of six members and returns to the laboratory. Each segment is paid as a one-way trip at a flat rate of \$9.35. The laboratory is entitled to a total of \$65.45 ( $7 \times \$9.35 = \$65.45$ ) but, since a separate claim must be submitted for each member, \$65.45 must be divided by the number of members, which is six. Each of the six members' claims would be submitted for \$10.91.
3. **Multiple members at a single address:** A laboratory representative travels from the laboratory to an apartment complex, draws blood from six members and returns to the laboratory. The laboratory is entitled to one round trip fee of \$18.70, but, since a separate claim must be submitted for each member, the \$18.70 must be divided by the number of members, which is six. Each of the six members' claims would be submitted for \$3.12.
4. **Multiple members at one address + one member at each of several additional sites:** A laboratory representative travels from the laboratory to an apartment complex and draws blood from three members; he then continues his circuit to three separate residences, and draws blood from one member at each, and returns to the laboratory. The laboratory should bill as follows:
  - The laboratory is entitled to \$9.35 for the trip segment from the laboratory to the apartment complex;
  - For each of the three members drawn at separate addresses, the laboratory is entitled to \$9.35 trip segment. The laboratory is also entitled to \$9.35 for the return to the laboratory. The total would be four times \$9.35, or \$37.40.

- The total number of stops are 5 (one stop from the laboratory to the apartment complex, stops at three members' homes and the return trip to the laboratory). The laboratory is entitled to a total of \$46.75 (5 x \$9.35 = \$46.75), but since a separate claim must be submitted for each member, \$46.75 must be divided by the number of members which is six. Each of the six members' claims would be submitted for \$7.79.

**Note:** For all examples, the amount charged and units to be billed per member must be entered on the claim. On the HCFA-1500 form, enter the amount charged in field 24H and enter two units in field 24G representing a round trip. For electronic claims the amount charged is reported as proprietary claim A, C3 Record, positions 35-41, and the units are reported as proprietary claim A, C3 Record, positions 25-26. For electronic HIPAA – 837P claims the amount charged is reported in Loop 2400, SV102 and the units in Loop 2400, SV104.

## Section III - Basis of Payment for Services Provided

The fees listed in the Laboratory Fee Schedule are applicable to holders of valid New York State clinical laboratory permits. Physicians, nurse practitioners, licensed midwives, and podiatrists who do not hold valid laboratory permits may provide only those services listed in the New York State Procedure Code Section and Fee Schedules contained in **their respective provider manuals**. Practitioners providing laboratory testing must be CLIA certified.

Payment to an independent clinical laboratory will only be made for tests ordered individually. For purposes of this ordering requirement, a panel defined by a single procedure code in the Medicaid Laboratory Manual is considered to be an individual test. This exception applies to the organ and disease panels in the Laboratory Procedure Code Manual at the following link:

<https://www.emedny.org/ProviderManuals/Laboratory/index.aspx>.

No payment will be made to a clinical laboratory for tests ordered as groupings or combinations of tests (e.g. panels, profiles) or for individual tests ordered on a test requisition form which also contains an order for one or more groups or combinations of tests.

Payment will only be made for tests actually performed and reported in writing to the ordering practitioner.

**Note: Medicaid will not reimburse for tests performed without a written order.**

### Payment for Repeat Laboratory Services

Repeat performance of a laboratory test or procedure required because of technical or professional error in the performance of the original test or interpretation of test results is not reimbursable.

No payment will be made for tests or procedures repeated on the same specimen at the request of the ordering practitioner when the result of the original test or procedure is not consistent with the clinical findings.

### Payment for Referred Laboratory Testing

State Regulations require that payment with respect to any item of medical care under Medicaid shall be made to the person or institution supplying such care. In specimen referral situations, Medicaid payment will only be made to the testing laboratory.

Medicaid offers some laboratories the option of submitting fee-for-service claims for testing performed by another laboratory.

A laboratory has the option to submit claims for reimbursement for tests performed by a reference laboratory **if** the forwarding laboratory and the reference laboratory are “subsidiary related” and both laboratories are enrolled in the Medicaid Program.

“Subsidiary related” means:

- The forwarding laboratory is a wholly owned subsidiary of the reference laboratory; or,
- The forwarding laboratory wholly owns the reference laboratory; or,
- Both the forwarding laboratory and the reference laboratory are wholly owned subsidiaries of the same entity.

For claims submitted for referred testing under this policy, payment will be made to the forwarding laboratory. **Note:** The Medicaid provider identification number of the laboratory that actually performed the testing must be entered on the claim submitted to Medicaid.

- This means that the forwarding laboratory must submit a separate claim for tests referred to a subsidiary laboratory. When billing with a Medicaid provider identification number, the license type field must be left blank.

For laboratories having a subsidiary relationship as defined above, the billing laboratory is held fiscally responsible for all laboratory claims submitted to Medicaid, including claims for testing referred to another laboratory. If the billing (forwarding) lab fails to provide correct and/or required information on the testing (reference) lab or the member, monies paid for reference testing may be subject to recoupment.

Both the forwarding laboratory and the testing laboratory must be currently enrolled in the Medicaid program. This is a billing policy change only; policy related to applications for enrollment into the Medicaid program is unchanged.

## Payment for Laboratory Services Provided by Hospitals and Other Article 28 Facilities

Medicaid payment rates for **hospital inpatient** stays include all laboratory tests provided to hospital inpatients. Accordingly, no laboratory procedures rendered to hospital inpatients are authorized to be billed separately to Medicaid on a fee-for-service basis. This policy is applicable to all laboratory tests which may be performed by the inpatient facility and to any and all laboratory tests referred by the inpatient facility to an outside (e.g. reference) testing laboratory. Any laboratory tests performed by a reference laboratory for a hospital inpatient must be billed directly to the inpatient facility.

Additionally, lab services are included in emergency department and outpatient hospital rates and may be included in diagnostic and treatment center (DT&C) rates. It is the responsibility of the laboratory to ensure inclusive charges are billed to the facility and not to Medicaid.

## Payment for Laboratory Services Available to the General Public at a Fixed Fee

In cases where a laboratory performs tests for members of the general public at a fixed fee, the laboratory will be reimbursed by Medicaid at that fixed fee or the established Medicaid maximum reimbursable amount, whichever is lower. If the service is provided to the general public free of charge, the laboratory must also make the service available to Medicaid members at no charge.

## Laboratory Services

**Comprehensive guidance on laboratory policies and covered services can be found on the NYS Medicaid Provider Manual website at the following link:**  
<https://www.emedny.org/ProviderManuals/Laboratory/index.aspx>

**Periodic updates to laboratory guidance is available on the NYS Medicaid Update website at the following link:**  
[https://www.health.ny.gov/health\\_care/medicaid/program/update/main.htm](https://www.health.ny.gov/health_care/medicaid/program/update/main.htm)

**Providers are encouraged to sign up for listserv notifications for these updates at the following link:**  
[https://www.emedny.org/Listserv/eMedNY\\_Email\\_Alert\\_System.aspx](https://www.emedny.org/Listserv/eMedNY_Email_Alert_System.aspx)

## Payment for Genetic Testing

Medicaid reimburses for genetic testing when performed by a **NYS Medicaid enrolled laboratory with a permit in Genetic Testing**. Please visit the following link



and review the laboratory fee schedule to determine if the specific CPT code for the test being ordered is included on the list.

<https://www.emedny.org/ProviderManuals/Laboratory/index.aspx>

Many genetic tests have specific criteria that must be met to be covered under NYS Medicaid. Providers must review Rule 14 at the link below prior to ordering genetic tests for their members.

[https://www.emedny.org/ProviderManuals/Laboratory/PDFS/Laboratory\\_Procedure\\_Codes.pdf](https://www.emedny.org/ProviderManuals/Laboratory/PDFS/Laboratory_Procedure_Codes.pdf)

## Genetic Counseling

Medicaid covers genetic counseling when provided by a certified or credentialed genetic counselor. A written order is required. Genetic counseling services may be provided in a practitioner's office or in an Article 28 hospital outpatient department (OPD) or diagnostic and treatment center (D&TC) or via telemedicine.

Reimbursement will be made to physicians, nurse practitioners, licensed midwives and Article 28 clinics who employ or contract with genetic counselors. Genetic counselors must be certified by the American Board of Genetic Counseling (ABGC), the American Board of Medical Genetics (ABMG) or be an advanced practice nurse in genetics (APNG), who is credentialed by the Genetic Nursing Credentialing Commission (GNCC). For additional information on genetic counseling, please visit the following link:

[https://www.health.ny.gov/health\\_care/medicaid/program/update/2015/2015-07.htm#gc](https://www.health.ny.gov/health_care/medicaid/program/update/2015/2015-07.htm#gc)

- Reimbursement for laboratory testing is limited to those procedures listed in the procedure code section.
- It is an unacceptable practice to bill Medicaid for tests actually performed by another laboratory, and/or to bill Medicaid for procedures or categories of procedures that are not included in your laboratory permit.

## Prior Approval

The New York State Medicaid Program does not require approval for provision of the laboratory services listed in the Procedure Code Section of the manual. However, codes listed as "By Report" (BR) on the fee schedule require the following information to accompany the claim: documentation outlining the need for the service and criteria (if applicable) has been met, the type of test performed, test results/reports, the number and source of the specimen(s) and documentation of the laboratory's usual and customary charge to the general public for the service.

## Unlisted Procedures

New York State fee-for-service reimbursement for laboratory testing is limited to those procedures listed in the Procedure Code Section of this Manual. Laboratories are reminded unlisted codes on the Laboratory Fee Schedule should not be used to submit claims that have been assigned a code by the American Medical Association (AMA).

## Utilization Threshold

The Utilization Threshold Program (UT) is a post payment review of services and procedures provided to members that evaluates medical necessity while maintaining fiscal responsibility to the Medicaid Program. For additional information please see the General Providers Policy Manual at:

[https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information\\_for\\_All\\_Providers-General\\_Policy.pdf](https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_All_Providers-General_Policy.pdf)

## Voluntary Compliance Program

Laboratories should establish a compliance program to ensure proper billing to Medicaid. If an error is discovered, voluntary disclosure should be made to the OMIG Self-Disclosure Unit at the following link: <https://omig.ny.gov/provider-resources/self-disclosure>.

## Laboratory Manual Policy Guidelines

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Disclosure will require laboratory repayment of any overpayment made by the Medicaid program. Voluntary disclosure will not prompt a full billing audit unless, upon review of the provider's billing records and payment history, a more systemic problem is identified.

## Section IV - Definitions

For purposes of the Medicaid Program and as used in this Manual, the following terms are defined:

### Clinic Outpatient

A clinic outpatient is one who is registered with a formally organized hospital or other Article 28 facility service unit known as a clinic. The clinic constitutes an organizational entity designed to provide diagnosis and/or treatment under the direction of a specialty or sub-specialty department of that hospital or other Article 28 facility but may only bill in accordance with the provisions stated.

### Clinical Laboratory

A clinical laboratory is a facility for the examination of materials derived from the human body (blood, urine, tissue, cells, hair, etc.) for the purpose of obtaining information for the diagnosis, prevention or treatment of disease or assessment of a health condition. Clinical laboratories may only perform tests in those categories included on their permit.

### Diagnostic and Treatment Clinic Laboratory

A diagnostic and treatment clinic laboratory is a laboratory located in an Article 28 certified diagnostic and treatment center. Such a laboratory may provide laboratory testing for the clinic's members, as well as for non-clinic members referred for ordered ambulatory laboratory testing.

### Employee

An employee is an individual who works for another, whether for salary or wages, the performance of whose services (including the results, details and means of accomplishment of those services) is controlled or directed by the person for whom the employee works.

### Hospital Laboratory

A hospital laboratory is a clinical laboratory operated by, or under the supervision of, a certified hospital or its organized medical staff and which serves the hospital's inpatients and/or outpatients. A laboratory serving hospital members and operated on the premises of a hospital is considered to be subject to the supervision of the hospital or its organized medical staff unless there is written evidence (i.e. contract) establishing the laboratory's independence of the hospital. Such a laboratory may provide laboratory testing for the hospital's inpatients and outpatients (e.g. clinic), as well as people referred for ordered ambulatory laboratory testing, but may only bill in accordance with the provisions stated above.

### Independent Laboratory

An independent laboratory is either a clinical laboratory, which is independent of a diagnostic and treatment center or a certified hospital laboratory or its organized medical staff. A laboratory physically located outside of a hospital is considered to be an independent laboratory unless there is written evidence establishing that it is operated by or under the supervision of a hospital.

### Laboratory Director

A laboratory director is the individual responsible for the administration of the technical and scientific operation of a clinical laboratory, including the supervision of procedures and reporting of test results. The Laboratory Director must have a valid Certificate of Qualification in one or more categories from the New York State Department of Health. The laboratory director must enroll as an individual with Medicaid. In the event that the enrolled director then leaves the laboratory Medicaid must be notified in writing. This written notification does not terminate the director's current Medicaid enrollment. If this director is employed at a new facility as a director he/she must submit the Laboratory Director's agreement document to Medicaid; however, if the director is enrolled as a physician only then re-enrollment as a laboratory director is required.

### Laboratory Ownership Interest

A laboratory ownership interest is the possession of equity in the capital, the stock or the profit of the laboratory. Ownership interest includes direct ownership, indirect ownership, controlling interest, corporate directorship or office, or partnership in a laboratory as defined in 18 NYCRR Part 502. Any change in the ownership of a laboratory provider must be reported within 15 days of the change by filing an amended, signed Ownership and Disclosure Form with the Department.

## Laboratory Permit

A laboratory permit refers to the approval issued by the New York State Department of Health, authorizing the operation of a clinical laboratory and required by Medicaid for a laboratory's participation as a provider. Permits are issued for various categories and types of testing and are subject to re-application annually, although changes may be affected throughout the year. Providers who lose their eligibility for participation may not bill Medicaid if the permit becomes void or invalid.

## Ordered Ambulatory Patient

An ordered ambulatory patient is one who is treated, tested and/or diagnosed in an ancillary services area (e.g., clinical laboratory) of a hospital or other Article 28 facility upon the referral of a physician or qualified practitioner who did **not** make that referral from a clinical outpatient or emergency outpatient area of that hospital or other Article 28 facility. An ordered ambulatory patient remains the patient of the community-based practitioner.

## Qualified Practitioner

A qualified practitioner is an individual, other than a physician, who:

1. provides services which are reimbursable pursuant to Section 365-a of the Social Services Law;
2. is authorized by law to order and use laboratory tests and the findings of laboratory examinations; and,
3. has not been excluded from participation in the Medicaid Program.

Practitioners meeting these criteria include dentists, podiatrists, nurse practitioners and certified midwives. A physician's assistant under the direction of a supervising physician may also order laboratory tests.

## Scope of Laboratory Services

All laboratory examinations, which must be medically necessary and related to the specific needs, complaints, or symptoms of the patient, require written order of a physician or qualified practitioner. Laboratory examinations initiated by the laboratory

based on the findings or test results of a preliminary procedure (“reflex testing”) are reimbursable only when ordered in writing by the ordering practitioner.

## Section V - Unacceptable Practices

### General Prohibitions

In addition to the guidelines that appear in **Information for All Providers, General Billing**, laboratories are specifically prohibited from engaging in practices considered unacceptable including, but not limited to, the following:

- Acceptance of specimens from an excluded ordering provider or laboratory;
- Payment or other consideration to practitioners for the referral of specimens;
- Payment of a percentage commission to sales personnel who are not employees of the laboratory. This prohibition is applicable to all non-employees of a laboratory including:
  - Independent contractors and management companies who may receive a fee for arranging or facilitating referral work to the laboratory;
- Operating a patient service center in a physicians' office, shared health facilities, or the offices or facilities of any other health services purveyor;
- Failure to report any change in ownership or control within 15 days of such change may result in termination of the provider's enrollment and require the newly constituted entity to enroll as a new provider;
- Supplying to enrolled physicians and qualified practitioners, at below fair market value, personnel (such as phlebotomists), billing services, or equipment unrelated to the collection of specimens (such as FAX machines, personal computers, medical waste disposal services, etc.) and supplies;
- Mailing on behalf of ordering practitioners "reminder" notices to members advising them to schedule appointments with their physician for follow-up laboratory testing;
- Selling pre-payment coupons, tickets, or booklets to physicians and qualified practitioners as advance payments for clinical laboratory services;
- Billing for procedures actually performed by another laboratory;
- Billing for procedures available free of charge to the general public;
- Billing for procedures covered by Federal, State or local grants;



- Billing for tests not properly ordered by a physician or qualified practitioner;
- Billing for procedures that were actually never performed;
- Billing for procedures prior to the reporting of final results to the physician or qualified practitioner;
- Billing for procedures or categories of procedures that are not included on the laboratory's permit.