Attachment 19

NEW YORK STATE
MEDICAID PROGRAM

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 recipients by one of the 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 recipients 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 recipients 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 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** 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
New York State Department of Health
Wadsworth Center
P.O. Box 509
Empire State Plaza
Albany, New York 12201-0509
518-485-5378
email: CLEP@health.ny.gov

Record Keeping Requirements

In addition to meeting the record-keeping requirements outlined, each clinical laboratory must retain for at least a six-year period the following documents:

- The original order form;
- The original test report.

If neither the original order nor test report is available then the laboratory must be able to produce a copy of the order form and/or test report.

Regulations for Laboratory Services

Regulations governing the delivery of laboratory services to Medicaid recipients 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.

Ordering Laboratory Services

A clinical laboratory may examine a specimen only when the test has been ordered by a licensed physician, a 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 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 licensed physician or qualified practitioner 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:

Recipient Information:

- Name
- Medicaid ID Number (CIN)
- Year of Birth
- Sex
- Medicare Number
- or Other Insurance Information

Ordering Practitioner Information:

- Medicaid ID Number (if not Medicaid enrolled use license number)
- Name
- Diagnosis (ICD-10-CM)
- Address
- Telephone Number
- Services Requested
- Date of Request

Indication if Service Related to:

- Accident

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

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. the 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):

- Recipients 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 recipient is restricted to a primary provider, all laboratory services must be ordered by that provider, or by a provider to whom the recipient 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 is eligible to participate 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 recipient 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

Effective for dates of service on or after July 1, 2003, 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.

This change in policy will make consistent the policies for claim submission of Medicaid and Medicare, thereby allowing laboratories to maintain one system for accessing and record keeping for specimens of individuals dually insured by Medicaid and Medicare.

Department rules at 10 NYCRR Subpart 59-1.11 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 person 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

Under the revised regulation, 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 recipients;

- Blood glucose testing for diabetics;

- Prothrombin and digoxin levels for cardiac recipients; 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 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. As a reminder, effective July 1, 2000, the following groupings of automated chemistry tests may be ordered as a panel:

- **Basic metabolic panel:**

    - This panel must include Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Urea nitrogen

- **Electrolyte panel:**

- This panel must include Carbon dioxide, Chloride, Potassium, Sodium

- **Comprehensive metabolic panel:**
  - This panel must include Albumin, Bilirubin total, Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Phosphatase alkaline, Potassium, Protein total, Sodium, Transferase, alanine amino, Transferase, aspartate amino, Urea nitrogen

- **Lipid panel:**
  - This panel must include Cholesterol, serum, total, Lipoprotein, direct measurement, high-density cholesterol, triglycerides

- **Renal function panel:**
  - This panel must include Albumin, Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Phosphorus, inorganic, Potassium, Sodium, Urea nitrogen

- **Hepatic function panel:**
  - This panel must include Albumin Bilirubin, total, Bilirubin, direct, Phosphatase, alkaline, Protein, total, Transferase, alanine amino, Transferase, aspartate amino.

Laboratory Service Provided In A Recipient'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 patient 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 recipient is eligible for in-home phlebotomy if:

- the recipient 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 recipient 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 patients in a skilled nursing facility;
- draw blood from a recipient 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 $7.50 one way, $15.00 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 recipients drawn at that location.
- There is a limit of 12 claims per recipient per year for in-home phlebotomy service; this allows for 12 round-trips or 12 one-way trips, or any combination of no more than 12 round or one-way trips.
- 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 $7.50 and divide this amount by the number of patients seen.

- The laboratory will pro-ration when the claim is submitted based on the number of patients seen on that trip.

- The "same 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 pro-rating for multiple recipients:

1. **One recipient at one site**: A laboratory representative travels from the laboratory to the home of one recipient 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 $15.00 (2 x $7.50 = $15.00).

2. **One recipient at each of multiple sites**: A laboratory representative travels in a circuit from the laboratory to the home of each of six recipients and returns to the laboratory. Each segment is paid as a one-way trip at a flat rate of $7.50. The laboratory is entitled to a total of $52.50 (7 x $7.50 = $52.50) but, since a separate claim must be submitted for each recipient, $52.50 must be divided by the number of recipients, which is six. Each of the six recipient claims would be submitted for $8.75.

3. **Multiple recipients at a single address**: A laboratory representative travels from the laboratory to an apartment complex, draws blood from six recipients and returns to the laboratory. The laboratory is entitled to one round trip fee of $15.00, but, since a separate claim must be submitted for each recipient, the $15.00 must be divided by the number of recipients, which is six. Each of the six recipients' claims would be submitted for $2.50.

4. **Multiple recipients at one address + one recipient at each of several additional sites**: A laboratory representative travels from the laboratory to an apartment complex and draws blood from three recipients; he then continues his circuit to three separate residences, and draws blood from one recipient at each, and returns to the laboratory. The laboratory should bill as follows:

    - The laboratory is entitled to $7.50 for the trip segment from the laboratory to the apartment complex;

    - For each of the three recipients drawn at separate addresses, the laboratory is entitled to $7.50 trip segment. The laboratory is also entitled

to $7.50 for the return to the laboratory. The total would be four times $7.50, or $30.00.

- The total number of stops are 5 (one stop from the laboratory to the apartment complex, stops at three recipients' homes and the return trip to the laboratory). The laboratory is entitled to a total of $37.50 (5 x $7.50 = $37.50), but since a separate claim must be submitted for each recipient, $37.50 must be divided by the number of recipients which is six. Each of the six recipient's claims would be submitted for $6.25.

Note: For all examples, the amount charged and units to be billed per recipient 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 Procedure Code Section of this Manual are applicable to holders of valid New York State clinical laboratory permits. Physicians 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, as appropriate, the **Medicaid Physician Manual** or **Medicaid Podiatry Manual**. Physicians and podiatrists 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.

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.

This change in policy does not affect the rate inclusiveness of laboratory testing, i.e., when recipients are hospital inpatients or receive clinic services in a facility where laboratory testing is included in the clinic reimbursement rate.

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 recipient, 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.

Medicaid payment for laboratory testing is not reimbursable on a fee-for-service basis if the cost of providing laboratory services has been included in the facility's all-inclusive Medicaid **emergency room or clinic rates**. A hospital or other Article 28 facility may, however, bill Medicaid for laboratory tests rendered to ordered ambulatory patients. **Such claims will only be reimbursed on a fee-for-service basis**. The clinic threshold rate may not be billed to Medicaid.

Furthermore, referral of an emergency or clinic outpatient to an ancillary service area of a facility does not change the classification of the patient to referred ambulatory status.

If a hospital or other Article 28 facility has been assigned an all-inclusive rate that includes the cost of laboratory services, Medicaid will not pay for any laboratory work that, while covered by the all-inclusive rate, has been referred by the facility to an outside laboratory. When this occurs the laboratory must seek reimbursement from the facility. See Section 2.2.5 for guidelines on reference testing.

Payment for Laboratory Services Provided by Government Laboratories

City, County and State government operated laboratories with a current valid New York State clinical laboratory permit may bill for services provided to recipients of Medicaid. Payment for laboratory services will be in an amount equal to the lower of: the amount specified in the Medicaid Fee Schedule for Laboratory Services or the fee charged for laboratory services provided to the general public by the laboratory. Laboratory services that are provided free of charge to the general public must also be provided free of charge to Medicaid recipients.

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 recipients at no charge.

Payment for Hepatitis C, HIV Viral Load and HIV Drug Resistance Tests

- Medicaid covers the HCV Genotypic assay and the HCV viral load test. **Medicaid reimbursement is limited to the federal Food and Drug Administration approved and home brew tests only.**

- Medicaid covers HIV viral load testing when clinically indicated, up to a maximum of six viral load tests per twelve month period per patient. Medicaid will reimburse for only one HIV viral load test per patient encounter.

- Laboratory providers may claim reimbursement for HIV drug resistance testing using the HIV virtual Phenotypic test. This testing is a covered service when clinically indicated, up to a maximum of three tests per recipient per patient treatment year.

Laboratories, Designated AIDS Centers, residential health care facilities and ordering practitioners are reminded of the following payment policies applicable to all laboratory testing, including HIV drug resistance, Hepatitis C and HIV viral load testing:

- Laboratories **may not bill** for tests performed **when patients are hospitalized.** Medicaid payment to the hospital includes all necessary laboratory services.

- All ordered **HCV genotype, HIV Viral Load and HIV drug resistance testing** are reimbursable fee-for-service directly to the testing laboratory. This includes tests ordered for:

    - Patients of Article 28 certified outpatient clinics,

    - Patients of designated AIDS centers operating under the Tier AIDS payment structure, and,

    - Inpatients of Article 28 residential health care facilities.

Medicaid regulations require that:

- Payment be made to the provider actually performing the test unless the reference laboratory and the forwarding laboratory are "subsidiary related" (see the information regarding subsidiary related in the section entitled "Payment for Referred Laboratory Testing" above); and

- Only Medicaid-enrolled clinical laboratories with Department of Health approval to perform HCV genotypic, qualitative and quantitative HCV viral load testing; HIV drug resistance testing; and/or HIV viral load testing are entitled to reimbursement.

    - All other ordered HCV quantitative viral load and HCV qualitative tests are reimbursable fee-for-service to the laboratory when such tests are ordered by a qualified practitioner from his/her office setting, or when such tests are not included in the clinic rate.

- If laboratory testing is included in the Article 28 clinic rate, the testing laboratory must seek payment from the clinic from which the test has been ordered.

Payment for Genetic Testing

A laboratory must hold a permit in Genetic Testing in order to bill for molecular diagnostic procedures (procedure codes 83890 – 83912).

- Molecular diagnostics codes are reimbursable for DNA-based genetic testing only. These codes are not reimbursable for non-genetic applications such as microbial detection or quantification, or testing for acquired changes in genetic material.

- Laboratory providers should refer to the procedure code section, rule number 14, for instructions on the proper use of procedure codes 83890 – 83912.

- When billing for organism specific antibody tests, use procedure codes in the 86000 series.

- When testing involves infectious agent detection by nucleic acid (DNA or RNA), use procedure codes 87449 – 87798. These codes include all steps of testing and reporting.

- 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.

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.

Utilization Threshold

The Utilization Threshold (UT) program places limits on the number of services a Medicaid member may receive in a benefit year. A benefit year is a 12-month period which begins the month the member became Medicaid eligible.

Medicaid members are assigned specific limits for the following services:

- Physician/Clinic Visits
- Laboratory Procedures
- Pharmacy
- Mental Health Clinic Visits
- Dental Clinic Visits

These service limits are established based on each member's clinical information. This information includes diagnoses, procedures, prescription drugs, age and gender. As a result, most Medicaid members have clinically appropriate service limit levels and will not need additional services authorized through the Threshold Override Application (TOA) process.

Additionally, in order to help avoid a disruption in a member's medical care, a "nearing limits" letter will be sent to the member. A nearing limits letter advises authorized services are being used at a rate that may exhaust the member's available services before completion of the current benefit year.

Determining Utilization Threshold Status

With the implementation of HIPAA 5010 and D.0 transactions, the DOH has eliminated the Service Authorization (SA - 278) process. This process required providers to obtain UT service authorizations via the Medicaid Eligibility Verification System (MEVS) prior to the payment of claims.

Since service authorization transactions are no longer being supported, the eligibility transaction process will provide information when the member is at limit.
Determining a Medicaid member's UT status is critical for accurate billing and payment purposes. The provider risks ***non payment*** if eligibility is not verified.

Eligibility Response

If a member has reached the Utilization Threshold limit for any service category, the eligibility response will return an indication of **"Limitations"** for the applicable Service Type(s). Laboratories may not submit a request for an increase in laboratory services. Such requests are to be submitted by the ordering provider. Laboratories which need to determine whether tests are needed on an emergency or urgent basis shall consult with the ordering provider, unless the order form indicates that an urgent or emergency situation exists.

If a "Limitations" message is returned, one of two options are available.

1. A Threshold Override Application (TOA) may be submitted to request an increase in the member's allowed services.
2. Services provided are exempt from the UT Program. See the **Services Exempt from the UT Program** section later in this document.

Technical Note: A "Limitations" Message is indicated by EB01 = 'F' for the Service Type identified in EB03.

Service Type Description	Service Type Code
Physician/Clinic	98
Laboratory	5
Pharmacy	88
Mental Health Clinic	MH
Dental Clinic	35

Utilization Threshold and Claims Processing

The member's service counts for each service category will be tracked based upon adjudication of the claim.

If during claim adjudication the member is at limits, the claim will pay if the UT units were available for the date of service when the eligibility request was processed.

If the provider did not perform an eligibility request for the date of service on the claim AND the member is at limits, the claim will be denied.

The NPI used when performing an eligibility request must match the NPI on the claim.

The exception to this is for providers who submit claims as a group. If either the group or rendering NPI was used to obtain the eligibility information and at least one of them match the claim, the UT edit will be bypassed.

NOTE: UT service limitations apply when billing Medicaid secondary claims (Medicare or other insurance primary).

The following service types and specialties are exempt from the UT Program.

► Drug Screen ►
Pap Smear

The following services are subject to the UT Program:

COS: 0162, 0281, 1000
Specialities: 400 THRU 599

Providers who have questions about what specialty codes they have on file may contact the eMedNY Call Center at 1-800-343-9000. The Call Center Representative may be able to give that information over the phone. In cases where the provider has too many specialty codes to be given over the telephone, the provider will be directed to request the specialty code list in writing.

There are circumstances where services that are subject to UT are considered exempt. These exceptions are detailed in the table below. When services are provided to a member who has exhausted their benefits and the circumstance exists, the applicable Service Authorization Exception Code must be provided on the claim.

HIPAA Code	HIPAA Description
1	Immediate/urgent
2	Services Rendered in Retroactive Period

3	Emergency Care
4	Member Has Temporary Medicaid
5	Request from County for 2nd Opinion to Determine if Member Can Work
6	Request for Override Pending
7	Special handling

Although providers no longer report their specialty code on claim transactions, specialty codes continue to be used internally to process claims. NYS Medicaid has implemented the use of Code 7 - Special handling to indicate the services were performed under a UT exempt Specialty Code.

Laboratories encountering urgent or emergency situations should see the override instructions in the Laboratory Billing Manual located at:

https://www.emedny.org/ProviderManuals/Laboratory/PDFS/Laboratory_Billing_Guidelines.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 Medicaid Division of Provider Relations at 518-474-9747. 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 patients, as well as for non-clinic patients 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 patients 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 and 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 patients 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.

Payment for Laboratory Services Provided to Hospitals and Clinics

Regulation 18 NYCRR 505.7(g)(7) states that no payment will be made on a fee-for-service basis for laboratory services when the cost of providing such services has been included in the Medicaid rate of payment for the provider of the patient care. Such providers include Article 28 hospitals (including hospital out-patient clinics) and free standing diagnostic and treatment centers. This regulation can be accessed on the internet at: http://www.health.ny.gov/nysdoh/phforum/nycrr18.htm

Billing on a fee-for-service basis for tests already included in a facility's rate structure is considered to be a duplicate payment and, as such, will be recouped by Medicaid.

When a lab enters into an agreement or arrangement with a facility, the agreement must include the use of a system of internal controls to allow determination of whether services are billable to Medicaid or billable back to the Article 28 facility.

There are also situations where one laboratory must refer specialized testing for inpatient, clinic, or ambulatory surgery patients to another lab. In these cases, the lab making the referral must identify hospital-based patients so that the testing lab knows which services are not to be billed to Medicaid.

Additionally, ordering identification numbers on claims must match those numbers on the fiscal order forms.