

Laboratory Services Table of Contents

John R. Kasich, Governor

John B. McCarthy, Director

Ohio Department of Medicaid

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Medicaid Handbook Transmittal Letters

MHTL 3345-10-01 (Disallowance of Separate Reimbursement for Blood-Glucose Testing in a Long-Term Care Setting)

Medicaid Handbook Transmittal Letter (MHTL) No. 3345-10-01

November 22, 2010

TO: Long-term care facilities
Independent laboratories
Other providers of laboratory services
Trading partners
Directors, County Departments of Job and Family Services

FROM: Douglas E. Lumpkin, Director

SUBJECT: Disallowance of separate reimbursement for blood-glucose testing in a long-term care setting

Policy Statement

Under current administrative rules governing laboratory tests, claims that are submitted to Medicaid by a long-term care facility (LTCF) for drawing blood specimens and for performing routine procedures are not separately reimbursable. Paragraph (B) of rule 5101:3-3-19 and paragraph (B) of rule 5101:3-3-19.1 of the Ohio Administrative Code specify that "costs incurred [by a long-term care facility]...for drawing specimens and forwarding specimens to a laboratory...are reimbursable through the facility's cost report" (i.e., payment is included in the facility's per diem amount). Paragraph (K)(1)(b) of rule 5101:3-11-03 of the Ohio Administrative Code states that "routine laboratory and screening procedures" are not reimbursable at all.

It is the policy of Ohio Medicaid that blood-glucose testing performed for a resident of a LTCF is a routine laboratory screening procedure. Therefore, it is not separately reimbursable to either LTCFs or independent laboratories. (Applicable procedure codes include but are not necessarily limited to CPT 36416 for taking a blood sample and CPT 82948 and 82962 for performing the analysis.)

Accordingly, neither LTCFs nor independent laboratories may submit claims for blood-glucose testing performed for LTCF residents. Even if the Medicaid claims-processing system should accept them, such claims are disallowed by policy. Any resulting reimbursement is subject to recovery.

Access to Rules and Related Material

The Ohio Department of Job and Family Services maintains an "electronic manuals" web page of the department's rules, manuals, letters, forms, and handbooks. The URL for this "eManuals" page is <http://emanuals.odjfs.state.oh.us/emanuals/>.

From the "eManuals" page, providers may view documents online by following these steps:

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Additional Information

Questions pertaining to this MHTL should be addressed to:

Office of Ohio Health Plans
Bureau of Provider Services
P.O. Box 1461
Columbus, OH 43216-1461
(800) 686-1516

MHTL 3345-09-02 (Community Provider Fee Decrease)

Medicaid Handbook Transmittal Letter (MHTL) No. 3345-09-02

January 8, 2010

TO: All Eligible Freestanding Laboratories
Directors, County Departments of Job and Family Services

FROM: Douglas E. Lumpkin, Director

SUBJECT: Community Provider Fee Decrease

This letter provides information regarding the amendment of Ohio Administrative Code (OAC) rules 5101:3-1-60, 5101:3-4-21.2, 5101:3-5-02, 5101:3-5-04, 5101:3-10-05, 5101:3-10-26, 5101:3-12-05 and 5101:3-12-06. These rules are being amended to comply with provisions of Amended Substitute House Bill 1 which reduced expenditures to certain community providers by an aggregate amount of three percent effective for dates of service on and after January 1, 2010. Total annual savings as a result of these reductions are estimated at approximately \$19,736,109.

OAC rule [5101:3-1-60](#), entitled Medicaid Reimbursement, sets forth payment amounts for services provided by a number of different community provider types including: advance practice nurses, ambulance and ambulette providers, ambulatory health care clinics, ambulatory surgery centers, chiropractors, dentists, durable medical equipment suppliers, freestanding laboratories, independent diagnostic testing facilities, occupational therapists, opticians, optometrists, orthotists, physical therapists, physicians, podiatrists, portable x-ray suppliers, psychologists and prosthetists. The payment reductions affecting specific provider types reimbursed through this rule are outlined below.

Ambulance and ambulette providers bill and are reimbursed on the basis of Healthcare Common Procedural Coding System (HCPCS) codes. The reimbursement amount for each of the HCPCS codes billed by these providers has been reduced by three percent, resulting in annual savings of approximately \$1,098,661.

Ambulatory surgery centers bill and are reimbursed on the basis of nine surgical groupings. The reimbursement amount for each of these nine groupings has been reduced by three percent, resulting in annual savings of approximately \$82,260.

Chiropractors bill and are reimbursed on the basis of Current Procedural Terminology (CPT) codes. The reimbursement amount for each of the CPT codes billed by chiropractors has been reduced by three percent, resulting in annual savings of approximately \$16,339.

Durable Medical Equipment (DME) suppliers bill and are reimbursed on the basis of HCPCS codes. The reimbursement amount for each of the adult incontinent garment HCPCS codes has been reduced by 10 percent resulting in an annual savings of approximately \$1,253,824. The reimbursement amount for each of the HCPCS codes for orthotics and prosthetics has been reduced by three percent, resulting in annual savings of approximately \$335,717.

Freestanding laboratories bill and are reimbursed on the basis of both CPT and HCPCS codes. The reimbursement amount for each CPT and HCPCS code billed by freestanding laboratories has been reduced by three percent, resulting in annual savings of approximately \$569,824.

Therapy services including those provided by physical, occupational and speech therapists are billed and reimbursed on the basis of CPT codes. The reimbursement amount for each of the CPT codes billed by these practitioners has been reduced by three percent, resulting in annual savings of approximately \$388,099.

Vision services provided by opticians, optometrists and physicians are billed and reimbursed on the basis of CPT codes. The reimbursement amount for each of the CPT vision codes billed by these practitioners has been reduced by three percent, resulting in annual savings of approximately \$228,490.

In addition to the reductions identified above, the maximum amount Medicaid will reimburse for any CPT code (i.e., the ceiling price) has been reduced from 100 to 90 percent of the Medicare price. This reduction affects 606 CPT codes and results in annual savings of approximately \$4,430,541. These 606 codes represent 10 percent of the 5,836 CPT codes billable to and reimbursed by Ohio Medicaid. Four hundred forty-five (74 percent) of the 606 codes were surgical codes, 94 (16 percent) were radiology codes, and 67 (11 percent) were medicine codes, of which 37 (55 percent) were cardiovascular in nature.

Providers of physician services bill and are reimbursed for the developmental testing of young children using CPT codes. The reimbursement amount for targeted developmental screening codes has been increased by 10 percent, resulting in an annual increase of expenditures of approximately \$21,321.

Two unrelated changes are being made to the pricing in 5101:3-1-60 at this time to comply with recent findings by the Auditor of State. The reimbursement amount for HCPCS code E0305, bed side rails, is being decreased from \$185.02 to \$185.01. The reimbursement amount for HCPCS code E2366, wheelchair battery charger, is being increased from \$202.00 to \$210.90. The impact of these changes on annual expenditures will be negligible.

OAC rule [5101:3-4-21.2](#), entitled Anesthesia Conversion Factors, sets forth payment amounts for services provided by anesthesiologists, anesthesia assistants and certified registered nurse anesthetists. These providers bill and are reimbursed on the basis of modifiers and conversion factors applied to CPT codes. The reimbursement rate for each of the conversion factors has been reduced by three percent, resulting in an annual savings of approximately \$194,457.

OAC rule [5101:3-5-02](#), entitled Dental Program: Covered Diagnostic Services and Limitations, sets forth the coverage criteria for oral examinations and diagnostic imaging in the dental program. Covered periodic oral examinations for adults age 21 years and older have been reduced from one every one hundred eighty days to one every 365 days, resulting in an annual savings of approximately \$200,946.

OAC rule [5101:3-5-04](#), entitled Dental Program: Covered Preventive Services and Limitations, sets forth the coverage criteria for preventive services in the dental program. Covered dental prophylaxis for adults age 21 years and older has been reduced from one every one hundred eighty days to one every 365 days, resulting in an annual savings of approximately \$491,720.

OAC rule [5101:3-10-05](#), entitled Reimbursement for Covered Services, sets forth among other things the manner in which providers may bill and be reimbursed for DME. Some DME items are not reimbursed according to the prices listed in 5101:3-1-60 but are instead reimbursed at the lesser of the provider's usual and customary charge or 75 percent of the list price presented to the department. This reimbursement level has been reduced by three percent, to 72 percent of the list price. When no list price is presented to the department, DME items are reimbursed at the lesser of the provider's usual and customary charge or one hundred fifty percent of the provider's invoice price less any discounts or applicable rebates. This reimbursement level has been reduced by three percent, to one hundred forty-seven per cent of the invoice price. These reductions in the percents paid of list and invoice prices are estimated to result in annual savings of approximately \$272,067.

OAC rule [3-10-26](#), entitled Enteral Nutritional Products, sets forth coverage criteria and reimbursement policies for enteral nutrition products. Some enteral nutrition products are not reimbursed according to the prices listed in 5101:3-1-60 but are instead reimbursed at the supplier's average wholesale price minus twenty percent. This figure has been reduced to minus twenty-three percent of the supplier's average wholesale price, resulting in annual savings of approximately \$285,921.

OAC rule [5101:3-12-05](#), entitled Reimbursement: Home Health Services, sets forth payment amounts for home health nursing, home health nursing aide, physical therapy, occupational therapy, and speech-language pathology. Home health service providers bill and are reimbursed on the basis of HCPCS codes. The reimbursement rate for each of these codes has been reduced by three percent, resulting in an annual savings of approximately \$5,676,688.

OAC rule [5101:3-12-06](#), entitled Reimbursement: Private Duty Nursing Services, sets forth payment amounts for private duty nurses. Private duty nurses bill and are reimbursed using a single HCPCS code. The

reimbursement amount for this code has been reduced by three percent, resulting in an annual savings of approximately \$4,231,876.

Web Page:

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Most current Medicaid maximum reimbursement rates are listed in rule [5101:3-1-60](#) or in Appendix DD to that rule. Providers may view these rates by:

- (1) Selecting the "Ohio Health Plans - Provider" folder;
- (2) Selecting "General Information for Medicaid Providers";
- (3) Selecting "General Information for Medicaid Providers (Rules)";
- (4) Selecting "5101:3-1-60 Medicaid Reimbursement" from the "Table of Contents" pull-down menu.

The Legal/Policy Central - Calendar site (<http://www.odjfs.state.oh.us/lpc/calendar/>) is a quick reference for finding documents that have recently been published. This site also provides a link to a listing of ODJFS manual transmittal letters (<http://www.odjfs.state.oh.us/lpc/mtl/>). The listing is categorized by letter number and subject, and a link is provided to each easy-print (PDF) document.

To receive electronic notification when new Medicaid transmittal letters are published, subscribe at: <http://www.odjfs.state.oh.us/subscribe/>.

Questions:

Questions pertaining to this letter should be addressed to:

Ohio Department of Job and Family Services
Office of Ohio Health Plans, Bureau of Provider Services
P.O. Box 1461
Columbus, OH 43216-1461
Telephone 800-686-1516

MHTL 3345-09-01

Medicaid Handbook Transmittal Letter (MHTL) 3345-09-01

May 15, 2009

TO: Independent laboratories
Portable x-ray suppliers
Independent diagnostic testing facilities (IDTFs)
Mammography suppliers
Directors, County Departments of Job and Family Services

FROM: Douglas E. Lumpkin, Director

SUBJECT: Five-Year Review of Rule 5101:3-11-02, Rescission and Adoption of Rule 5101:3-11-02, and Amendment of Rule 5101:3-11-01

This Medicaid Handbook Transmittal Letter (MHTL) transmits rule [5101:3-11-01](#), now titled *Definitions: independent laboratory, portable x-ray supplier, independent diagnostic testing facility (IDTF), and mammography supplier*, and rule [5101:3-11-02](#), now titled *Provider requirements: independent laboratory, portable x-ray supplier, independent diagnostic testing facility (IDTF), mammography supplier, and other providers of laboratory services*. The effective date of both these rules is 1 June 2009.

Changes

Rule 5101:3-11-02 is being rescinded and a new version adopted in accordance with the five-year review provisions set forth in section 119.032 of the Ohio Revised Code. Rule [5101:3-11-01](#) is being amended to maintain consistency with rule [5101:3-11-02](#). Improvements have been made in paragraph structure and organization, in clarity of phrasing, and in referencing of external sources. Mammography suppliers are more clearly distinguished from independent diagnostic testing facilities (IDTFs), but for billing and payment purposes within the Ohio Medicaid program, they continue to be treated as the same provider type.

Access to Rules and Related Material

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Additional Information

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Office of Ohio Health Plans
Bureau of Provider Services
P.O. Box 1461

Columbus, OH 43216-1461

800-686-1516

MHTL 3345-08-01

Medicaid Handbook Transmittal Letter (MHTL) 3345-08-01

March 28, 2008

To: Providers of Laboratory Services
Directors, County Departments of Job and Family Services
Medical Assistance Coordinators

From: Helen E. Jones-Kelley, Director

Subject: Update of Specimen Collection Procedure Codes and New Coverage of Laboratory Procedures

Changes

Ohio Administrative Code rule 5101:3-11-03, *Laboratory services: coverage and limitations*, is being amended. Paragraph (F)(6) of this rule lists procedure codes that are recognized for specimen collection. One code is being removed from that list:

36540 Collection of blood specimen from partially or completely implantable venous access device

Two new procedure codes are being added:

36591 Collection of blood specimen from a completely implantable venous access device

36592 Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified

Since January 1, 2008, a number of laboratory procedures have been newly covered under Medicaid. Because of a delay, however, in the publication of the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Fee Schedule, reimbursement amounts were unavailable for seven procedures:

CPT Code	Description
80047	Metabolic panel, ionized Ca
82610	Cystatin C
83993	Assay for fecal calprotectin
84704	HCG, free beta chain test
86356	Mononuclear cell antigen, quant., NOS
87500	Vancomycin, DNA, amplified probe
87809	Adenovirus assay w/ optic

These seven procedures have been reimbursed "by report," which has required the filing of paper claims on the CMS 1500 form. As of April 1, 2008, Medicaid maximum reimbursement amounts are established for these procedures and are listed in Appendix DD to rule 5101:3-1-60, *Medicaid reimbursement*. Claims for these procedures with dates of service on or after April 1 may be billed electronically.

Web Page:

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Providers may view documents online by:

- (1) Selecting the "Ohio Health Plans - Provider" folder;

- (2) Selecting "Laboratory Services" from the document list; and
- (3) Selecting the desired item from the "Table of Contents" pull-down menu.

Most current Medicaid maximum reimbursement rates are listed in rule 5101:3-1-60 or in Appendix DD to that rule. Providers may view these rates by:

- (1) Selecting the "Ohio Health Plans - Provider" folder;
- (2) Selecting "General Information for Medicaid Providers";
- (3) Selecting "5101:3-1-60 Medicaid Reimbursement" from the "Table of Contents" pull-down menu;
and
- (4) Selecting the link to Appendix DD located near the bottom of the web page.

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Paper Distribution:

Providers will receive one printed copy of this transmittal letter and an accompanying JFS 03400, "Ohio Department of Job and Family Services, Service Provider Update Request Form." Providers may request a second printed copy of this letter and a copy of rule 5101:3-11-03 by completing the JFS 03400 and returning it to the Ohio Department of Job and Family Services in accordance with the instructions at the top of the form.

Additional Information

Questions pertaining to this letter should be addressed to:

Office of Ohio Health Plans
Provider Services Section
P.O. Box 1461
Columbus, OH 43216-1461
(800) 686-1516

MHTL 3345-04-01

Medicaid Handbook Transmittal Letter (MHTL) 3345-04-01

December 31, 2003

TO: All Providers of Laboratory Services
Directors, County Department of Job and Family Services
Medical Assistance Coordinators

FROM: Thomas J. Hayes, Director

SUBJECT: Handbook Update For 2004 HCPCS Changes

The purpose of this Medicaid Handbook Transmittal Letter (MHTL) is to announce the implementation of the 2003 HCPCS codes and to notify providers of updates to the Ohio Medicaid Provider Handbook to providers of laboratory services.

On January 1, 2004, the department will begin accepting the 2004 HCPCS codes for services rendered on or after that date. **The department will not accept 2003 HCPCS codes for services rendered after December 31, 2003.**

Handbook section, LAB.1101.61 titled, Clinical Laboratory Procedures Codes, and LAB.1101.62 titled, Anatomical Pathology Codes contain tables of codes that are considered by the department to be clinical or anatomical codes respectively. These tables include both Medicaid covered and non-covered laboratory codes and have been updated to include the 2004 HCPCS codes. To determine whether a code in one of the tables is Medicaid covered or to find the Medicaid maximum payment rate, please reference Appendix DD of rule 5101:3-1-60 of the Administrative Code. For your reference, the covered 2004 laboratory HCPCS codes have been classified below as clinical or anatomical codes:

2004 New Medicaid Covered Clinical Codes

2004 New Medicaid Covered Clinical Codes	
84156	87329
84157	87660
85055	89225
85396	89235
87269	

2004 New Medicaid Covered Anatomical Codes

88112

88361

In addition, the following laboratory manual appendices have been updated:

- **LAB.1152 Diagnostic and Therapeutic Codes Requiring Modifiers**
- **LAB.1151 Clinical Laboratory Procedure Codes Which Commonly Require Pathology Consultative Services (Code 85396 was added.)**

Requesting updates to this manual

The manual updates that are announced in this MHTL can be found on our website at:
<http://emanuals.odjfs.state.oh.us/emanuals> or if you do not have internet access you may request a paper copy of the rules by completing the attached JFS 03400.

Questions pertaining to this MHTL should be addressed to:

Bureau of Plan Operations

The Provider Network Management section

P.O. Box 1461

Columbus, Ohio 43216-1461

Toll free telephone number 1-800-686-1516

MHTL 3345-03-01

Medicaid Handbook Transmittal Letter (MHTL) 3345-03-01

October 17, 2003

TO: All Providers of Laboratory Services
Directors, County Department of Job and Family Services
Medical Assistance Coordinators

FROM: Thomas Hayes, Director

SUBJECT: Laboratory Handbook- Revisions to Anatomical Pathology Billing Procedures

The purpose of this Medicaid Handbook Transmittal Letter (MHTL) is to announce updates to the rules which govern laboratory services. Revisions include the elimination of the ZP modifier to denote the total procedure, the implementation of the TC modifier to denote the technical component and the deletion of certain procedure codes. The department recently discovered that Independent Laboratories did not receive the original announcement of these revisions. Clinical laboratories were accidentally omitted when this announcement was originally distributed. The department regrets any inconvenience this may have caused and is reviewing their distribution process to ensure this omission will not happen in the future.

Laboratory code changes - LAB.1101

For dates of services on or after July 1, 2003, unmodified anatomical procedures went from meaning the technical only component to meaning the total procedure (both the professional and technical component).

Total Procedure

- **For services rendered on or after July 1, 2003, the Department will no longer recognize the ZP modifier since it is not H.I.P.A.A.-compliant. Providers billing for the total anatomical pathology code (i.e., both the professional and technical components) must bill the appropriate HCPCS code unmodified. Reimbursement for the total anatomical pathology procedure will be the lesser of the provider's total charged amount or the Medicaid maximum as set forth in Appendix DD of rule 5101:3-1-60.**
- **For services rendered prior to July 1, 2003, reimbursement of the total procedure will be made when providers bill the most appropriate code for the anatomical pathology procedure modified by the modifier ZP (e.g., 88300ZP).**

Technical Component Only

- **To bill for the technical component for anatomical pathology codes, for services rendered on or after July 1, 2003, providers performing and billing for the technical component only must bill the appropriate code modified by the modifier TC (e.g., 88300TC)**
- **For services rendered prior to July 1, 2003, when an eligible provider of laboratory services performs only the technical component of an anatomical procedure, the provider may bill for the technical component by billing the appropriate code unmodified.**

Deletion of Certain Procedure Codes

- **As of July 1, 2003, the department revised the anatomical pathology code list to delete certain obsolete anatomical pathology codes. The obsolete codes are 85102, 88170.**

Requesting updates to this manual

The manual updates that are announced in this MHTL can be found at on our website at: <http://dynaweb.odjfs.state.oh.us:6336/dynaweb/medicaid> or if you do not have internet access you may request a paper copy of the rules by completing the attached JFS 03400. If you have received ONLY a paper copy of this MHTL and you wish to be notified in the future by e-mail of program updates the week that they are published, please send an email to: provider_subscribe@odjfs.state.oh.us and include your provider number.

Questions pertaining to this MHTL should be addressed to:

Bureau of Plan Operations

The Provider Network Management section

P.O. Box 1461

Columbus, Ohio 43216-1461

In-state toll free telephone number 1-800-686-6108

Out-of-state telephone number 1-614-728-3288

MHTL 3345-02-01

Medicaid Handbook Transmittal Letter (MHTL) 3345-02-01

January 8, 2002

TO: All Providers of Laboratory Services
Directors, County Department of Job and Family Services
Medical Assistance Coordinators

FROM: Thomas Hayes, Director

SUBJECT: Handbook Update for 2002 HCPCS Changes

2002 HCPCS HANDBOOK UPDATE

- **Update: Most commonly asked questions about Medicaid**
- **H.I.P.A.A**
- **Waived lab tests**
- **Appendices updates**

The purpose of this Medicaid Handbook Transmittal Letter (MHTL) is to announce the implementation of the 2002 HCPCS (including CPT and alpha-numeric) codes and to transmit a new consolidated Chapter 3345 of the Ohio Medicaid Provider Handbook to providers of laboratory services.

2002 HCPCS Codes

On January 1, 2002, the Department began accepting the 2002 HCPCS codes effective for services rendered on and after that date. To give providers time to make the transition to the 2002 HCPCS codes, the Department will continue to accept the 2001 codes for services rendered through March 31, 2002. Providers may choose to bill either the 2002 codes or the 2001 codes during the transition period from January 1, 2002 to March 31, 2002. Beginning April 1, 2002, the 2000 codes will no longer be accepted to report services provided on and after that date.

Most Commonly Asked Questions Update

This section is now entitled "Top Fifteen Questions". The Department has added answers to five commonly asked questions noted as questions 11-15. These questions address issues including Medicare/Medicaid claim issues, "zero-pay" notations on a remittance advice, H.I.P.A.A. and provider address changes.

Health Insurance Portability and Accountability Act (H.I.P.A.A)

To learn more about H.I.P.A.A., there has been a web site created by Ohio's statewide H.I.P.A.A. committee. Please check the following web site address for educational materials including an awareness brochure: <http://www.state.oh.us/hipaa/educationalmaterials.htm> (*the hardcopy erroneously cites this URL as <http://www.state.oh.us.hipaa/educationalmaterials.htm>*)

Laboratory Services Handbook Update

The following is a summary of the significant policy and/or handbook changes that have been made effective for January 1, 2002 and are incorporated into the attached consolidated Chapter 3345 of the Provider Handbook. Please review the bolded, bulleted headlines listed below and read those sections of the handbook that pertain to the services your particular practice provides. You will find black lines in the left-hand margin of applicable pages indicating changes made. This MHTL and all changes made to the consolidated Chapter 3345 will be available on the web in January, 2002 at <http://dynaweb.odjfs.state.oh.us:6336/dynaweb/medicaid>.

Policy Clarifications/ Changes:

Appendix I (LAB.1150) Waived Laboratory Procedures

This appendix has been updated to include lab procedures which CLIA has indicated may be billed using the QW modifier which indicates that the lab procedure is a waived procedure under CLIA. The procedures which are new waived procedures are underlined and have an asterisk beside them in this appendix. Procedures which were discontinued as waived are noted at the bottom of the waived procedure section of this appendix. A current list of waived lab tests or PPMP tests can be found on the CLIA web site at <http://www.hcfa.gov/medicaid/clia/cliahome.htm> under the section entitled "Categorization of tests under CLIA". The Medicare intermediary also publishes updates to the list of waived tests in their monthly newsletters.

Appendices:

- **The following appendices have been revised as a result of the implementation of the 2002 HCPCS updates:**

LAB.1150 Waived Laboratory Procedure Categories
LAB.1151 Clinical Laboratory Procedures for Which Pathology Consultations are Allowed
LAB.1152 List of Diagnostic and Therapeutic Codes with Professional/ Technical Splits

Questions pertaining to this MHTL should be addressed to:

Bureau of Plan Operations

The Provider Network Management Section

P.O. Box 1461

Columbus, OH 43216-1461

In-state toll free telephone number 1-800-686-6108

Out-of-state telephone number 1-614-728-3288

MHTL 3345-01-02

Medicaid Handbook Transmittal Letter (MHTL) 3345-01-02

June 8, 2001

TO: All Providers of Laboratory, Physiological Lab, and Portable X-ray Services
Directors, County Department of Job and Family Services
Medical Assistance Coordinators

FROM: Greg L. Moody, Director

SUBJECT: Handbook Update

LABORATORY, PHYSIOLOGICAL LAB, AND PORTABLE X-RAY SERVICES

HANDBOOK UPDATE

EFFECTIVE AUGUST 1, 2001

- **Definitions: Independent Diagnostic Testing Facility (IDTF)**
- **Independent Laboratory**
- **Independent Mammography Supplier**
- **Eligible Providers of IDTF Services**
- **Conditions for Coverage for IDTF Services**
- **Portable X-ray Suppliers: Conditions for Coverage**
- **Ordering of Laboratory Services**
- **Specimen collection**
- **Laboratory Specimens Sent to the Ohio Department of Health**

The purpose of this Medicaid Handbook Transmittal Letter (MHTL) is to announce updates to the rules governing independent laboratories, independent diagnostic testing facilities (formerly known as physiological laboratories), and x-ray suppliers. Updated handbook sections are attached. New information is noted by a vertical line to the left of the new language.

Updated Definitions:

The definition of an independent laboratory has been expanded to clarify that a facility which only collects or prepares specimens or only serves as a mailing service and does not perform any tests are not considered laboratories.

The provider type physiological laboratory has been changed to independent diagnostic testing facility (IDTF) in accordance with the Medicare terminology change. The definition of an IDTF for Medicaid billing purposes is now "Independent diagnostic testing facility" means a facility for the performance of diagnostic tests which are performed by licensed or certified nonphysician personnel under appropriate physician supervision. The facility may be a fixed location, a mobile entity, or an individual nonphysician practitioner and in all cases must comply with applicable state law. An "independent diagnostic testing facility" is a facility which is independent of the attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center or a hospital. An independent diagnostic testing facility under the ownership and direction of a physician is considered an independent diagnostic testing facility if the physician holds himself and the facilities of his office out to other physicians as being available for the performance of diagnostic tests.

The definition of an independent mammography supplier has been expanded to clarify that these providers must meet the certification requirements of section 354 of the Public Health Services Act and must have a valid certificate that has been issued by the FDA. Under the Ohio Medicaid program, all independent mammography suppliers are considered IDTFs.

IDTFs:

The conditions of coverage for IDTFs have been updated and many of the conditions currently in place by Medicare have been adopted. The new conditions of coverage are as follows:

- **An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the facility including the qualifications of the nonphysician personnel, the operation and calibration of the equipment, and the quality of the testing performed. The supervising physician must personally furnish supervision whether the procedure is performed at a fixed location or a mobile facility.**
- **Diagnostic testing services may be covered if the following conditions are met:**
 - The physician providing general supervision of the services has attained board certification in the appropriate specialty or the physician who is not board certified must document completion of a training program approved by a recognized accrediting body and evidence proficiency in the tests being supervised as required by the appropriate specialty and described in Medicare regulations.
 - All nonphysician personnel must demonstrate the basic qualifications to perform the tests and have training and proficiency as evidenced by licensure or certification by the appropriate state department. If no state board exists for the testing in question, then certification by an appropriate national credentialing body is acceptable.
- **The provisions addressing the coverage of IDTF services has been expanded to specify that the services must be requested in writing by the treating physician or treating non-physician provider, e.g advanced practice nurse, in accordance with state law. Services may be performed under a verbal order but the IDTF must obtain a written order before the service is billed to the Department. Staff at the IDTF may not add any procedures based on internal protocols without a written order by the treating practitioner.**
- **Covered IDTF procedures are limited to tests specified in Medicare regulations for IDTFs. If the specific CPT code for the service is not listed in Medicare's IDTF regulations, it is not a covered service under the Medicaid program.**

Portable X-ray Suppliers:

Portable X-ray suppliers may perform diagnostic mammograms if the provider meets the requirements listed in 21 CFR Part 900 Subpart B.

For a portable x-ray supplier's services to be covered, the services must be performed under the general supervision of a physician.

Laboratory Services:

Policies addressing coverage for laboratory services have been amended to address the ordering of laboratory services. Laboratory services are covered only if they are performed at the written or electronic request of an authorized person.

- **The laboratory procedure may be performed on the verbal order of the treating physician or treating non-physician provider, e.g advanced practice nurse, in accordance with state law. The laboratory must obtain a written order that is dated and signed by the treating practitioner before the Department is billed. The laboratory must maintain the written authorization in their records for a period of six years or until any initiated audit has been completed as specified Ohio Revised Code 5101: 3-1-172. If the patient's medical record is used as a test requisition, it must be maintained for six years and must be available to the laboratory at the time of the testing and available to the Department upon request.**
- **The laboratory must assure that the requisition or test authorization includes:**
 - The patient's name;

- The name and address of the authorized person requesting the test, and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen;
 - The test to be performed;
 - The date of the specimen collection;
 - For pap smears, the patient's last menstrual period, age, or date of birth, and indication of whether the patient had a previous abnormal report, treatment, or biopsy; and
 - Any additional information necessary to a specific test to assure accurate and timely testing and reporting.
- **The laboratory which performed the test must meet all laboratory standards outlined in 42 CFR 493.**

A new code has been recognized for specimen collection. It is 36540 and is defined as "collection of blood specimen from partially or completely implantable venous access device". In addition, the code P9605, venipuncture for a homebound or nursing home patient is no longer a covered service.

Providers who send laboratory specimens to ODH may not bill the Department. Providers who use the state laboratory must complete the top portion of the HCFA 1500 claim form and include any attachments required by ODH and the ODH state laboratory will complete the claim form and submit the claim for payment. This is a clarification of an existing policy.

Questions pertaining to this MHTL should be addressed to:

Bureau of Plan Operations

The Provider Network Management section

P.O. Box 1461

Columbus, Ohio 43216-1461

In-state toll free telephone number 1-800-686-6108

Out-of-state telephone number 1-614-728-3288

MHTL 3345-01-01

Medicaid Handbook Transmittal Letter (MHTL) 3345-01-01

January 24, 2001

TO: All Providers of Laboratory Services
Directors, County Department of Job and Family Services
Medical Assistance Coordinators

FROM: Jacqueline Romer-Sensky, Director

SUBJECT: Handbook Update for 2001 HCPCS Changes

2001 HCPCS HANDBOOK UPDATE

- **Mammography services**
- **Appendices updates**

The purpose of this Medicaid Handbook Transmittal Letter (MHTL) is to announce the implementation of the 2001 HCPCS (including CPT and alpha-numeric) codes and to transmit a new consolidated Chapter 3345 of the Ohio Medicaid Provider Handbook to providers of podiatry services.

2001 HCPCS Codes

On January 1, 2001, the Department began accepting the 2001 HCPCS codes effective for services rendered on and after that date. To give providers time to make the transition to the 2001 HCPCS codes, the Department will continue to accept the 2000 codes for services rendered through March 31, 2001. Providers may choose to bill either the 2000 codes or the 2001 codes during the transition period from January 1, 2001 to March 31, 2001. Beginning April 1, 2001, the 2000 codes will no longer be accepted to report services provided on and after that date.

Laboratory Services Handbook Update

The following is a summary of the significant policy and/or handbook changes that have been made effective for January 1, 2001 and are incorporated into the attached consolidated Chapter 3345 of the Provider Handbook. Please review the bolded, bulleted headlines listed below and read those sections of the handbook that pertain to the services your particular practice provides. You will find black lines in the left-hand margin of applicable pages indicating changes made. This MHTL and all changes made to the consolidated Chapter 3345 will be available on CD-ROM in February, 2001.

Policy Clarifications/Changes:

- **Mammography Services - LAB.1104**

Effective January 1, 2001, the Department has expanded its mammography coverage to allow for annual screenings for women ages 40 and over.

Appendices:

- **The following appendices have been revised as a result of the implementation of the 2001 HCPCS updates:**

LAB.1150 Waived Laboratory Procedure Categories
LAB.1151 Clinical Laboratory Procedures for Which Pathology Consultations are Allowed
LAB.1152 List of Diagnostic and Therapeutic Codes with Professional/ Technical Splits

Questions pertaining to this MHTL should be addressed to:

Bureau of Plan Operations

The Provider Network Management Section

P.O. Box 1461

Columbus, OH 43216-1461

In-state toll free telephone number 1-800-686-6108

Out-of-state telephone number 1-614-728-3288

MHTL 3345-99-6

Medicaid Handbook Transmittal Letter (MHTL) 3345-99-6

TO: All Providers of Laboratory Services
Directors, County Departments of Human Services
Medical Assistance Coordinators

FROM: Wayne W. Sholes, Director

SUBJECT: Handbook Update for 1999 HCPCS Changes
1999 HCPCS Changes Handbook Update
Specimen Collection
Clinical and Anatomical Pathology Procedures
QW Modifier for Waived Laboratory Tests
Billing Exceptions for Hospital Outpatients
New ODHS 6768 Claim Credit Reversal Form
HCFA 1500 Date Format Changes
Appendix Updates

The purpose of this Medicaid Handbook Transmittal Letter (MHTL) is to announce the implementation of the 1999 HCPCS (including CPT and alpha-numeric) codes and transmit a new consolidated Chapter 3345 of the Ohio Medicaid Provider Handbook to providers of laboratory services.

1999 HCPCS Codes

On January 1, 1999, the Department began accepting the 1999 HCPCS codes effective for services rendered on and after that date. To give providers ample time to make the transition to the 1999 HCPCS codes, the Department will continue to accept the 1998 codes for services rendered through March 31, 1999. Providers may choose to bill either the 1998 codes or the 1999 codes during the transition period from January 1, 1999 to March 31, 1999. Beginning April 1, 1999, the 1998 codes will no longer be accepted to report services provided on and after that date.

Laboratory Services Handbook Update

The following is a summary of the significant policy and/or handbook changes that have been made effective for January 1, 1999, and are incorporated into the attached consolidated Chapter 3345 of the Provider Handbook. Please review the bolded, bulleted headlines listed below and read those sections of the handbook that pertain to the services your particular practice provides. You will find black lines in the left-hand margin of applicable pages indicating changes made to the handbook. This MHTL and all changes made to the consolidated Chapter 3345 will be available on CD-ROM in January, 1999.

- **CLIA Certification**

In order for claims for laboratory services to be paid to eligible providers, the Department must have an accurate record of your CLIA certification. A CLIA registration form was recently sent to those providers for whom the Department had no record of their CLIA number. If you are one of these providers and have not yet returned this form, please do so as soon as possible. If you have returned this form to the Department and are still receiving inappropriate denials for laboratory services which are covered by your CLIA certification, please contact the Department at the number listed below.

If you are a CLIA-certified provider and are receiving denials from Medicaid for laboratory services because:

- 1.) the Department has no record of your CLIA certification, or

2.) the service that was billed is not permitted with the certificate type the Department has on file for your provider number,

and you believe that these denials are inappropriate, please contact the Department to verify and/or update your CLIA information by calling the Provider Enrollment Unit at (800) 686-6108 for In-State callers or (614) 728-3288 if you are calling from out-of-state. Select Option 2 on the voice menu in order to reach the Provider Enrollment Unit.

- **Specimen Collection - LAB.1101.7**

HCPCS code P9610, catheterization for collection of specimen(s), single homebound, nursing home or SNF patient, has been deleted. It has been replaced with P9612, catheterization for collection of specimen, single patient. This should be used to report specimen collection for homebound, nursing home or SNF patients.

- **QW Modifier for Waived Laboratory Tests - LAB.1150.**

The Department has added the "QW" modifier to the claims payment system which should be used when billing for certain laboratory procedure codes to indicate that the laboratory test was performed using a test system or procedure categorized as waived under the Clinical Laboratory Improvement Amendments (CLIA). Please see the updated appendix LAB.1150. for a list of procedures considered waived under CLIA and for those procedures which may be billed using the "QW" modifier.

- **Clinical and Anatomical Pathology Procedures - LAB.1101.6**

Please refer to LAB.1101.61 and LAB.1101.62 for updated lists of clinical and anatomical pathology laboratory procedure codes.

- **Billing Exceptions for Hospital Outpatients - LAB.1101.10**

For hospital outpatients, hospital providers may bill for clinical laboratory procedures they do not actually perform when the procedures are referred to and performed by a laboratory that is certified to perform the service under the Clinical Laboratory Improvement Amendments (CLIA).

When clinical laboratory services for hospital outpatients are performed by a reference laboratory, the referring hospital provider must have a written arrangement with the reference laboratory that specifies which provider will bill the Department for the laboratory services. If the hospital provider bills for a clinical laboratory service performed by a reference laboratory, the reference laboratory must not bill either Medicaid or the beneficiary for its service. If the reference laboratory bills for the clinical laboratory service, the referring hospital must not bill either Medicaid or the beneficiary for the service.

In the event that the Department issues payment to both the referring hospital and the reference laboratory for the same clinical laboratory service, the Department will make the assumption that the payment issued to the reference laboratory is subject to recovery.

Billing Instructions

- **Eight Digit Date Format - LAB.1202. Medicaid Claim Form HCFA 1500**

Providers submitting claims on the HCFA 1500 form may now enter either a 6 digit (MMDDYY) or an 8 digit (MMDDCCYY) date for items requiring dates on this form. **This option is for paper/hard copy claim submission only** and will assist in accommodating reporting requirements for the year 2000. The electronic billing formats, ANSI and NSF, are already compliant for the year 2000.

- **ODHS 6768 Form - LAB.1210. Claim Credit Reversal Form**

Instructions for completing the Claim Credit Reversal Form, ODHS 6768, have been added to the billing instructions. The Claim Credit Reversal Form is used to process full credit adjustments for which the provider is returning the entire Medicaid payment amount. The ODHS 6768 does not replace Claims Adjustment Forms ODHS 6767 and ODHS 6766, but rather is an additional form that is used only to reverse the entire amount of a payment. The ODHS 6768 form cannot be used to resubmit claims that have been previously submitted to the Claims Adjustment Unit on the ODHS 6767 and ODHS 6766 forms and are pending processing.

Appendices

- **Waived Laboratory Procedure Codes - LAB.1150.**

This appendix has been updated to include those laboratory procedure codes which may be billed using the QW modifier to indicate the procedure was considered a waived procedure under CLIA.

- **Clinical Laboratory Procedures For Which Pathology Consultations are Allowed - LAB.1151.**

This appendix has been updated to include all clinical laboratory procedure codes for which the Department will reimburse a provider for the interpretation of the laboratory procedure if the physician is not the patient's attending physician.

- **List of Diagnostic and Therapeutic Codes with Professional and Technical Components - LAB.1152.**

Appendix LAB.1152. has been revised as result of the implementation of the 1999 HCPCS updates.

Questions pertaining to this MHTL should be addressed to:

The Provider Relations Section

P.O. Box 1461

Columbus, Ohio 43266-0161

In-state toll free telephone number: 1-800-686-6108

Out-of-state telephone number: 1-614-728-3288

Miscellaneous Medicaid Handbook Transmittal Letters

MHTL 3334-10-02

Medicaid Handbook Transmittal Letter (MHTL) No. 3334-10-02 (New 2010 HCPCS and CPT Codes and Policy Updates), is maintained in the General Information e-book.

[Click here to view MHTL 3334-10-02, New 2010 HCPCS and CPT Codes and Policy Updates](#)

MHTL 3334-09-02

Medicaid Handbook Transmittal Letter (MHTL) No. 3334-09-02 (Discontinuing the Disability Medical Assistance (DMA) Program and the Rescission of Ohio Administrative Code (OAC) Rule 5101:3-23-01), is maintained in the General Information e-book.

[Click here to view MHTL 3334-09-02, Discontinuing the Disability Medical Assistance \(DMA\) Program and the Rescission of Ohio Administrative Code \(OAC\) Rule 5101:3-23-01](#)

Medical Assistance Letters

MAL 532

Medical Assistance Letter No 532 (June 7, 2007 - Information Providers Must Know about the National Provider Identifier (NPI) in Order to Get Paid), is maintained in the Ambulatory Surgery Center Services e-book.

[**Click here to view MAL 532, Information Providers Must Know about the National Provider Identifier \(NPI\) in Order to Get Paid.**](#)

MAL 522

Medical Assistance Letter No 522 (August 14, 2007 - Guidance on the Implementation of Employee Education about False Claims Recovery as provided in MAL 516), is maintained in the General Information e-book.

[Click here to view MAL 522, August, 2007 - Guidance on the Implementation of Employee Education about False Claims Recovery as provided in MAL 516.](#)

MAL 516

Medical Assistance Letter No 516 (November 9, 2006 - Employee Education About False Claims Recovery), is maintained in the General Information e-book.

[Click here to view MAL 516, Employee Education About False Claims Recovery.](#)

MAL 501

Medical Assistance Letter (MAL) No. 501

October 25, 2006

To: All Laboratory Services
Directors, County Departments of Job and Family Services
Medical Assistance Coordinators

From: Barbara E. Riley, Director

Subject: Laboratory Services

The purpose of this Medical Assistance Letter (MAL) is to notify laboratory services of rules that have been reviewed to maintain compliance with Section 119.032 of the Revised Code, which requires the review of state agency rules within a five-year period. The rules included in the review are:

Rule 5101:3-11-01, Independent laboratory, x-ray supplier and independent diagnostic testing facility: definitions;

Rule 5101:3-11-04, Laboratory: exceptions for FQHCs, RHCs, OHFs, and hospital outpatients;

Rule 5101:3-11-05, Laboratory specimens sent to the Ohio department of health (ODH) state laboratories;

Rule 5101:3-11-06, Portable x-ray suppliers: covered services and limitations;

Rule 5101:3-11-07, Independent diagnostic testing facility: coverage and limitations.

A few changes to the rules were made to update and clarify language and grammar. Rule 5101:3-11-05 previously referenced the HCFA form; the rule now references the CMS 1500. Other changes to the Chapter 5101:3-11 rules include updating the reimbursement procedures for Independent Diagnostic Testing Facilities to be consistent with the CMS standards, and adding the definition for the Clinical Laboratory Improvement Amendment (CLIA).

The updates that are announced in this Medical Assistance Letter (MAL) can be found on our website at <http://emanuals.odjfs.state.oh.us/emanuals/medicaid> in Laboratory Services.

Providers will receive one hard copy of this letter, and one hard copy of the JFS 03400 "Ohio Department of Job and Family Services, Service Provider Update Request Form." If a provider does not have access to the Internet and wishes to request a paper copy of this letter with copies of Ohio Administrative Code rules 5101:3-11-01, 5101:3-11-04, 5101:3-11-05, 5101:3-11-06, and 5101:3-11-07, the Provider should complete the attached JFS 03400 and return it to the Ohio Department of Job and Family Services according to the instructions at the top of the form.

Questions pertaining to this MAL should be addressed to:

Bureau of Plan Operations

Provider Network Management Section

PO Box 1461

Columbus, Ohio 43216-1461

In-State toll free telephone number 1-800-686-1516

Attachment

[Click here to view the order form for MAL 501.](#)

MAL 496

Medical Assistance Letter (MAL) No. 496

March 9, 2006

TO: All Laboratory Service Providers
Directors, County Departments of Job and Family Services
Medical Assistance Coordinators

FROM: Barbara E. Riley, Director

SUBJECT: Laboratory 2006 HCPCS Update

EFFECTIVE JANUARY 1, 2006

The purpose of this Medical Assistance Letter (MAL) is to notify Laboratory service providers of updates to CPT procedure codes. The procedure codes to be added are: 80195, 82271, 82272, 83037, 83631, 83695, 83700, 83701, 83704, 83900, 83907, 83908, 83909, 83914, 86200, 86355, 86357, 86367, 86480, 86923, 86960, 87209, 87900, 88333, 88334, 88384, 88385, 88386, and 89049.

Laboratory codes that are waived procedure codes include 83037, 83721, 83880, 85576, 86703, and 87807.

The laboratory procedure codes to be deleted are: 82273, 83715, 83716, 86064, 86379, 86585, and 86587.

The following codes that have been added and are anatomical codes are 88333, 88334, 88384, 88385, and 88386.

The list of procedure codes that have a replacement code are listed below.

Deleted Procedure Code	New or Revised Procedure Code
82273	82271
83715	83700
83716	83701
86064	86355
86379	86357
86585	86580
86587	86367

The procedure codes can be found in rule 5101:3-1-60 of the Administrative Code. The procedure codes for clinical laboratory that allow separate reimbursement for interpretive consultation can be found in rule 5101:3-11-03. The procedure codes for radiology that are subject to CLIA are located in rule 5101:3-11-10. This Medical Assistance Letter (MAL) can be found on our website at <http://emanuals.odjfs.state.oh.us/emanuals/medicaid>.

Providers will receive one hard copy of this letter, and one hard copy of the [JFS 03400](#) "Ohio Department of Job and Family Services, Service Provider Update Request Form." If a provider does not have access to the Internet and wishes to request a paper copy of this letter with copies of Ohio Administrative Code rules 5101:3-11-03 and 5101:3-11-10, the Provider should complete the attached JFS 03400 and return it to the Ohio Department of Job and Family according to the instructions at the top of the form.

Questions pertaining to this MAL should be addressed to:

Bureau of Plan Operations

Provider Network Management Section
P.O. Box 1461
Columbus, OH 43216-1461
In-State toll free number: 1-800-686-1516

Attachment

[Click here to view the order form for MAL 496.](#)

MAL 477

Medical Assistance Letter (MAL) No. 477

March 8, 2005

TO: All Providers of Independent Laboratories
Directors, County Department of Job and Family Services
Medical Assistance Coordinators

FROM: Barbara E. Riley, Director

SUBJECT: ANATOMICAL LABORATORY CODES

The purpose of this Medical Assistance Letter (MAL) is to announce the new anatomical laboratory codes and to transmit any new policy changes resulting from these changes to eligible providers of laboratory services. These changes are based on the emergency rule filing that was effective 12/30/04. The permanent rule is effective 1/16/05.

New Anatomical Laboratory Codes:

There are new anatomical lab codes added by the AMA for 2005: They are 88187, 88188, 88189, 88360, 88367, and 88368. These codes will be added to the anatomical lab code table now found under the section called "billing and coding aids." Please use modifier 26 when billing for the professional component.

These changes have been posted to the department's web site at <http://emanuals.odjfs.state.oh.us/emanuals/medicaid> in Laboratory Services

Questions pertaining to this MAL should be addressed to:

Bureau of Plan Operations

The Provider Network Management Section

P.O. Box 1461

Columbus, Ohio 43216

In-state toll free telephone number 1-800-686-1516

MAL 465

Medical Assistance Letter (MAL) No. 465

April 23, 2004

TO: All Providers of Laboratory Services
Directors, County Departments of Job and Family Services
Medical Assistance Coordinators

FROM: Thomas J. Hayes, Director

SUBJECT: Medicaid Rules for Laboratory Services

The purpose of this Medical Assistance Letter is to notify providers of laboratory services that two laboratory rules have been amended, and that some laboratory codes and their Medicaid maximum rates found in rule 5101:3-1-60 have been changed to comply with the National Laboratory Fee Schedule requirements. The newly amended rules are effective April 1, 2004.

Rule 5101:3-11-03 titled, Laboratory Services: Coverage and Limitations, was amended to include an additional procedure code, 36416 collection of capillary blood specimen, and to revise the description of procedure code, 36415 collection of venous blood by venipuncture. Both codes are recognized for specimen collection and were revised in accordance with 2003 CPT codes and descriptions. Although code 36416 is now being added to laboratory rule 5101:3-11-03, it has been a reimbursable procedure listed in appendix DD of rule 5101:3-1-60 for dates of service on or after July 1, 2003.

In addition, the department has reinstated reimbursement for neonatal diagnostic screening kits. The department will recognize code S2630 for the reimbursement of the screening kits used on or after February 1, 2003.

Rule 5101:3-11-08, titled, Reimbursement for Laboratory, Portable X-Ray Supplier, and Independent Diagnostic Testing Facilities, has been amended so that language pertaining to reimbursement for the technical and professional component of anatomical pathology procedures is consistent with the professional/technical split indicator format in appendix DD of rule 5101:3-1-60. This does not involve any changes to the Medicaid maximum reimbursement rates for anatomical pathology procedures.

HCPCS code, G0026, will be discontinued effective April 1, 2004. Instead, providers with a CLIA certification for PPM procedures may bill for the fecal leukocyte assessment using code, 89055, which is effective for dates of service on or after July 1, 2003. Either code may be billed for dates of service between July 1, 2003 and April 1, 2004.

Effective April 1, 2004 the Medicaid maximum reimbursement rates for eight laboratory codes contained in appendix DD of rule 5101:3-1-60 have been adjusted according to the revised 2004 Laboratory Fee Schedule issued in December by the Centers for Medicare and Medicaid Services (CMS). The affected codes are:

84156 Protein, Total, Except Refractometry; Urine

84157 Protein, Total, Except Refractometry; Other

85055 Reticulated Platelet Assay

87269 Infectious Agent Antigen Detection By Immunofluorescent Technique; Giardia

87329 Enzyme Immunoassay (EIA), Qualitative/Semiquantitative, Multiple Step; Giardia

87660 Infectious Agent, Nucleic Acid (DNA/RNA); Trichomonas Vaginalis, Direct Probe

89225 Starch Granules, Feces

89235 Water Load Test

To obtain a copy of the rules and future program updates:

The rules that are announced in this Medical Assistance Letter (MAL) can be found on our website at: <http://emanuals.odjfs.state.oh.us/emanuals> or if you do not have internet access you may request a paper copy of the rules by completing the attached [JFS 03400](#).

Questions pertaining to this MAL should be addressed to:

**The Bureau of Plan Operations
Provider Network Management Section
P.O. Box 1461
Columbus, Ohio 43216-1461
Toll-free number: 1-800-686-1516**

Attachment

[Click here to view the JFS 03400, Health Plan Provider Update Request Form for MAL 465.](#)

Laboratory Rules

5160-11-01 Definitions: Independent Laboratory, Portable X-Ray Supplier, Independent Diagnostic Testing Facility (IDTF), and Mammography Supplier

***Formerly* 5101:3-11-01 Definitions: Independent Laboratory, Portable X-Ray Supplier, Independent Diagnostic Testing Facility (IDTF), and Mammography Supplier**

MHTL 3345-09-01

Effective Date: June 1, 2009

Most Current Prior Effective Date: May 25, 2006

(A) "Independent laboratory" means a facility established for the biological, microbiological, ~~immunological, immunohematological~~, serological, chemical, ~~immunohematological~~, hematological, biophysical, cytological, pathological, or other examination of materials of the human body for the purpose of ~~providing~~ obtaining information for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of ~~an individual's~~ the health of, human beings. ~~An "independent laboratory" is a facility that~~ It is independent of the an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. A laboratory under the ownership and direction of a physician or physician group, such as a pathologist(s), is considered to be an independent laboratory if the physician holds himself or herself and the facilities of his or her office out to other physicians as being it is represented to other physicians that both the physician-owner(s)/director(s) and the facility are available for the performance of laboratory procedures. Facilities that only ~~collecting or preparing~~ collect or prepare specimens or that function only ~~servicing~~ performing as a mailing service and do not ~~performing~~ perform testing are not considered to be laboratories.

~~(B) Independent portable x-ray supplier.~~

(B) ~~portable~~ "Portable x-ray supplier" means an entity established for the ~~performance~~ provision of diagnostic x-ray ~~procedures when the~~ services ~~are provided~~ in a ~~patient's~~ consumer's place of residence.

~~(C) Independent diagnostic testing facility.~~

~~(1)~~(C) "Independent diagnostic testing facility (IDTF)" means a facility or an entity established for the performance of diagnostic tests that are ~~performed~~ conducted by licensed or certified nonphysician personnel under appropriate physician supervision. ~~The facility~~ An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner, ~~and in all cases must comply with applicable state law. The "independent diagnostic testing facility" must meet all standards and provide services in accordance with 42 C.F.R. 410.33 (October 1, 2005). An "independent diagnostic testing facility" is a facility that~~ It is independent of the an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. An independent A diagnostic testing facility under the ownership and direction of a physician or physician group is considered to be an independent diagnostic testing facility if ~~the physician holds himself or herself and the facilities of his or her office out to other physicians as being~~ it is represented to other physicians that both the physician-owner(s)/director(s) and the facility are available for the performance of diagnostic tests.

~~(2)~~(D) ~~An "independent mammography~~ "Mammography supplier" means a facility or an entity established solely for the ~~single purpose of performing~~ provision of mammography services. ~~An "independent mammography supplier" is a facility or entity which that is independent of the attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital and meets the certification requirements of Section 354 of the Public Health Services Act as implemented by 21 CFR C.F.R. (April 1, 2005) part 900, subpart B and has a valid certificate that has been issued by the U.S. food and drug administration (FDA). Under~~ For billing and payment purposes within the Ohio medicaid program, all independent a mammography ~~suppliers are considered~~ supplier is treated as an independent diagnostic testing facilities facility.

Effective: 06/01/2009

R.C. 119.032 review dates: 05/01/2011

Certification: CERTIFIED ELECTRONICALLY

Date: 05/05/2009

Promulgated Under: 119.03

Statutory Authority: 5111.02

Rule Amplifies: 5111.01, 5111.02, 5111.021

Prior Effective Dates: 04/07/1977, 05/09/1986, 02/17/1991, 07/01/1993, 08/01/2001, 05/25/2006

5160-11-02 Provider Requirements: Independent Laboratory, Portable X-Ray Supplier, Independent Diagnostic Testing Facility (IDTF), Mammography Supplier, and Other Providers of Laboratory Services

***Formerly* 5101:3-11-02 Provider Requirements: Independent Laboratory, Portable X-Ray Supplier, Independent Diagnostic Testing Facility (IDTF), Mammography Supplier, and Other Providers of Laboratory Services**

MHTL 3345-09-01

Effective Date: June 1, 2009

Most Current Prior Effective Date: February 1, 2003

(A) General requirements for participation.

- (1) An entity is eligible to participate in the medicaid program as an independent laboratory, a portable x-ray supplier, or an independent diagnostic testing facility (IDTF) and to provide covered services if it satisfies the following requirements:**
 - (a) It must conform to the appropriate definition set forth in rule 5101:3-11-01 of the Administrative Code;**
 - (b) It must have executed the standard Ohio medicaid provider agreement in accordance with rule 5101:3-1-17.2 of the Administrative Code; and**
 - (c) It must comply with all applicable state laws.**
- (2) Any eligible medicaid provider included in the following list or otherwise certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) may provide and be reimbursed for covered laboratory procedures appropriate to its level of certification.**
 - (a) Ambulatory health care clinic;**
 - (b) Ambulatory surgery center (ASC);**
 - (c) Federally qualified health center (FQHC);**
 - (d) Outpatient health facility (OHF);**
 - (e) Outpatient hospital laboratory;**
 - (f) Physician or physician group practice;**
 - (g) Podiatrist or podiatric group practice; or**
 - (h) Rural health clinic (RHC).**

(B) Specific requirements for reimbursement.

A participating entity is eligible for reimbursement if it satisfies additional requirements.

- (1) An independent laboratory must meet the following criteria:**
 - (a) It must meet the standards of compliance listed at 42 C.F.R. 493.3 (effective April 24, 2003).**
 - (b) It must perform covered procedures that are appropriate to its level of certification.**
 - (i) A provider possessing only a certificate of waiver may be reimbursed only for waived procedures.**
 - (ii) A provider possessing only a certificate for provider-performed microscopy (PPM) procedures may be reimbursed only for waived and PPM procedures.**
 - (iii) A provider possessing a certificate of registration, a certificate of compliance, or a certificate of accreditation may be reimbursed for:**
 - (a) Waived procedures;**
 - (b) PPM procedures;**

- (c) Tests of moderate complexity, if the provider meets the applicable requirements set forth in 42 C.F.R. 493.20 (effective September 22, 2003); and
 - (d) Tests of high complexity, if the provider meets the applicable requirements set forth in 42 C.F.R. 493.25 (effective September 22, 2003).
 - (2) A portable x-ray supplier must comply with the conditions for coverage set forth in 42 C.F.R. part 486, subpart C (sections 486.100, 486.102, 486.104, 486.106, and 486.108 effective February 8, 1995; section 486.110 effective September 29, 1995).
 - (3) An independent diagnostic testing facility (IDTF) must meet the following criteria:
 - (a) It must meet all standards set forth in and provide services in accordance with 42 C.F.R. 410.33 (effective January 15, 2008).
 - (b) It must be a party to a current, unrevoked, and unsuspended agreement to participate in medicare as an independent diagnostic testing facility (IDTF).
 - (c) It must take the following measures to establish accountability:
 - (i) It must ensure that each supervising physician certifies in writing, at the time of the initial application and at each renewal of the Ohio medicaid provider agreement, that one of two statements is true:
 - (a) The physician owns the facility, in whole or in part, and employs the operating personnel; or
 - (b) The physician is an employee of the facility (full-time, part-time, or under contract) whose responsibilities include checking the procedure and quality control manuals; observing the performance of operators or technicians; verifying that the equipment and personnel meet applicable federal, state, and local licensure and registration requirements; and ensuring that safe operating procedures and quality control procedures are used.
 - (ii) It must maintain and update procedure and quality control manuals. All records of quality control must be kept for the period of time specified in paragraph (D) of rule 5101:3-1-17.2 of the Administrative Code.
 - (4) A mammography supplier must meet the following criteria:
 - (a) It must participate in the medicaid program as an independent diagnostic testing facility (IDTF).
 - (b) It must comply with the conditions for coverage set forth in 42 C.F.R. 410.34 (effective October 31, 1997).

Replaces: 5101:3-11-02

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APPENDIX

[Click here to view the 5160-11-03 Laboratory Services Appendix](#)

- (A) Laboratory services include:
- (1) Biological, microbiological, serological, chemical, immunological, immunohematological, hematological, cytological, or pathological procedures performed on specimens from the human body;
 - (2) Specimen collections as defined in paragraph (F) of this rule; and
 - (3) Electrocardiogram (ECG/EKG) services when they are performed by certified independent laboratories.
- (B) A laboratory service is covered only if:
- (1) The test is medically necessary as defined in rule 5101:3-1-01 of the Administrative Code, or the test is medically indicated when provided in conjunction with a covered preventive health service as defined in rule 5101:3-4-02 of the Administrative Code;
 - (2) The laboratory which performed the procedure is certified to perform the procedure under the medicare program in accordance with the "Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)"; and
 - (3) The laboratory service is performed at the written or electronic request of an authorized practitioner.
 - (a) The laboratory procedure may be performed on the verbal order of a physician but the laboratory must obtain a written order before the department is billed. The laboratory must maintain the written authorization.
 - (b) A copy of the written order must be kept on file by the laboratory for a period of six years as described in rule 5101:3-1-17.2 of the Administrative Code. When laboratory services are performed by the physician's office, group practice, clinic, or a hospital (for hospital inpatients and outpatients), the orders may be written by an authorized person in the patient's medical records. The patient's medical record, if used as the test requisition, must be retained for a minimum of six years and must be available to the laboratory at the time of testing and available to the department upon request.
 - (c) The laboratory must assure that the requisition or test authorization includes:
 - (i) The patient's name;
 - (ii) The name and address of the authorized person requesting the test, and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen;
 - (iii) The test to be performed;
 - (iv) The date of the specimen collection;
 - (v) For pap smears, the patient's last menstrual period, age, or date of birth, and indication of whether the patient had a previous abnormal report, treatment, or biopsy; and

- (vi) Any additional information necessary to a specific test to assure accurate and timely testing and reporting.
 - (d) Laboratory tests that must be performed as follow-up to a result of a test that was ordered do not need the written order of a physician as long as the follow-up procedure meets standard and appropriate laboratory practices and is included as part of the laboratory's written protocols. For example, an antibody panel and direct coombs performed after a positive antibody screen or a quantitative test performed after a positive qualitative test.
 - (e) The laboratory which performed the test must meet all laboratory standards outlined in 42 C.F.R. 493 (October 1, 2005).
- (C) Except as provided for in rule 5101:3-11-04 of the Administrative Code, providers, including hospitals providing services to hospital outpatients and independent laboratories, may bill the department only for those laboratory procedures they actually perform.
- (D) A physician or clinic may be reimbursed only for the following laboratory services:
- (1) Clinical pathology procedures and specimen collection actually performed in the physician's office, physician's group practice, or clinic;
 - (2) The professional component of anatomical pathology procedures;
 - (3) The total anatomical pathology procedure when the physician operates a full-service, in-office laboratory certified to perform both the technical and professional components, and the services are performed on a nonhospital patient;
 - (4) Clinical pathology consultative services;
 - (5) Services performed by a physician in personal administration of test devices, isotopes, or other materials to an individual patient.
- (E) Laboratory procedures are divided into two categories: clinical laboratory procedures and anatomical pathology procedures. The department will determine which procedures are considered clinical laboratory procedures and anatomical pathology procedures.
- (1) Clinical laboratory procedure codes.
 - (a) To bill for clinical laboratory procedures, the provider must bill the most appropriate code for the procedure (unmodified). Clinical laboratory codes may not be billed with a modifier.
 - (b) Providers must use the codes for organ- or disease-oriented panels.
 - (i) When a laboratory/provider performs all of the tests included in a panel, a panel code must be billed. Providers may not bill separately for each of the tests included in a panel code.
 - (ii) If a laboratory/provider performs a panel of tests and other tests in addition to those specifically listed as included in the panel code, the additional tests may be billed separately in addition to the panel code.
 - (iii) When a provider performs some, but not all of the tests identified in a panel, the provider may not bill the panel code but must bill separately for each of the tests performed using the appropriate codes.
 - (iv) Panels for preventive health screenings are only reimbursable when provided to children under the healthcheck program.
 - (c) Providers must use the codes for certain organ- or diseased- oriented panels when all the tests listed as included in that panel code are performed.
 - (d) If a laboratory/provider performs other tests in addition to those specifically listed as included in a panel code, the additional tests may be billed in addition to the panel code.

Inclusion of additional tests in a laboratory's/provider's own definition of a panel code does not justify the medical need for the test or the coverage of the test under medicaid.

- (e) Providers may not bill nor be reimbursed for clinical laboratory procedures performed on hospital inpatients even if the laboratory procedures were performed by a laboratory outside the hospital. Clinical laboratory procedures performed on hospital inpatients are reimbursed in accordance with paragraph (E) of rule 5101:3-11-08 of the Administrative Code.

(2) Anatomical pathology codes.

- (a) For the purpose of the medicaid program, the term "anatomical pathology" has been extended to include all laboratory services which require the total involvement or the partial involvement of a physician in the performance of the procedure.
- (b) Anatomical pathology codes can be identified as those codes for which there is a professional/technical indicator in appendix DD of rule 5101:3-1-60 of the Administrative Code.
- (c) A professional and technical component is recognized for each anatomical pathology procedure. When both components are provided by one provider, the laboratory service is defined as the total procedure.
- (d) When anatomical pathology procedures are performed on a hospital outpatient or a hospital emergency room patient, the hospital must bill for the technical component and the physician, or an eligible provider billing on behalf of the physician, must bill for the professional component of the procedure, even if the services were performed by a laboratory outside the hospital.
- (e) When anatomical pathology procedures are furnished to hospital inpatients, the services are covered in accordance with paragraph (E) of rule 5101:3-11-08 of the Administrative Code.
- (f) Total procedure.

For services rendered on or after July 1, 2003, the department will no longer recognize the ZP modifier.

- (i) The total procedure must be billed when both components of an anatomical pathology procedure are performed by a nonhospital provider. Neither hospitals nor hospital-based physicians may bill for the total anatomical pathology procedure.
 - (ii) For services rendered on or after July 1, 2003, reimbursement for the total anatomical pathology procedure will be the lesser of the provider's total charged amount or the medicaid maximum for the appropriate code.
 - (iii) For services rendered prior to July 1, 2003, reimbursement of the total procedure will be made when providers bill the most appropriate code for the anatomical pathology procedure modified by the modifier ZP (e.g., 88300ZP)
- (g) Professional component.
- (i) The professional component recognized by the department for an anatomical pathology procedure is for the professional services a physician renders in the performance of the laboratory procedure and not for the interpretation of the laboratory results as they relate to the patient's condition. The interpretation of laboratory results is a part of the care rendered when the physician provides and bills for a physician service such as a visit or a surgery.
 - (ii) Since the professional component of an anatomical procedure is a physician service, only eligible providers of physician services and independent laboratories billing on behalf of their physicians (e.g., physician-owners, staff physicians, or

physicians under contract with the laboratory) may bill for the professional component of an anatomical pathology procedure.

- (iii) For reimbursement of the professional component (only), the provider must bill the service using a professional claim format in accordance with rules 5101:3-1-19.1 and 5101:3-1-19.2 of the Administrative Code using the code for the anatomical pathology procedure modified by the modifier 26 (e.g., 8830026).
- (iv) The following anatomical pathology services are exclusively physician professional services and must always be billed using a professional claim format in accordance with rules 5101:3-1-19.1 and 5101:3-1-19.2 of the Administrative Code claim as the professional component using the 26 modifier:
 - (a) Clinical pathology consultations;
 - (b) Physician interpretation of a bloodsmear;
 - (c) Physician interpretation of a bone marrow smear;
 - (d) Blood bank physician services;
 - (e) Consultative services on referred materials and/or slides.

(h) Technical component

- (i) The hospital must bill for the technical component of all anatomical pathology procedures performed on a hospital inpatient, a hospital outpatient, or a patient of the hospital emergency room.
- (ii) For services rendered on or after July 1, 2003, the department will no longer recognize the modifier ZP. Providers performing only the technical component must bill the appropriate code modified by the modifier TC (e.g., 88300TC).
- (iii) For services rendered prior to July 1, 2003, when an eligible provider of laboratory services performs only the technical component of an anatomical procedure, the provider may bill for the technical component by billing the appropriate code unmodified.

(F) Specimen collection.

- (1) Reimbursement for drawing and collecting certain specimens is allowable up to a the maximum which is specified in rule 5101:3-1-60 of the Administrative Code. This fee includes the collection, handling and shipping of specimens. The collection fee may be paid only to the provider who extracted the specimen from the patient. Only one collection fee is allowed for each patient encounter per body site regardless of the number of samples drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series will be treated as a single encounter.
- (2) Payment for the specimen collection is independent of the payment for the laboratory procedure. The provider who performed the specimen collection is entitled to payment regardless of where the laboratory procedure was performed.
- (3) Specimen collection is covered as a laboratory service only in the following circumstances:
 - (a) Drawing a blood sample by venipuncture;
 - (b) Collecting a urine sample by catheterization; or
 - (c) Drawing a blood sample by capillary puncture when the specimen collected is used for the same diagnostic tests as would a specimen drawn by venipuncture but the later is not feasible because of medical complications.
- (4) Specimen collection is not covered in the following circumstances:
 - (a) Collecting a routine urine sample;
 - (b) Collecting a routine culture sample;

- (c) Collecting a blood sample by capillary puncture when the procedure is a part of the test procedure (e.g., bleeding time); or
 - (d) Collecting a pap smear or other tissue sample (except when there is a separate code available for the tissue excision).
- (5) When the service is provided in a long-term care facility or a private home, specimen collection is covered as long as:
- (a) The provider personally draws the specimen and is not an employee of the long-term care facility; and
 - (b) The patient is either homebound or confined to the long-term care facility;
- (6) The following procedure codes are recognized for specimen collection:
- 36415 Collection of venous blood by venipuncture.
- 36416 Collection of capillary blood specimen (e.g., finger, heel, ear stick)
- ~~36540 Collection of blood specimen from partially or completely implantable venous access device.~~
- 36591 Collection of blood specimen from a completely implantable venous access device
- 36592 Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified
- P9612 Catheterization for collection of specimen, single patient all places of service.
- P9615 Catheterization for collection of specimen(s) (multiple patients).
- (7) The department will not reimburse providers for travel expenses associated with the collection of specimens.
- (G) Clinical pathology consultative services.
- (1) A physician, usually a pathologist or hematologist, may be reimbursed for clinical pathology consultations by billing the codes for clinical pathology consultations.
 - (2) Clinical pathology consultative services must:
 - (a) Be requested by the patient's attending physician;
 - (b) Relate to one of the clinical laboratory tests listed in appendix A of this rule or to a test result that lies outside clinically significant normal or expected range in view of the patient's condition;
 - (c) Result in a written narrative report prepared by the consulting physician included in patient's medical record; and
 - (d) Require medical interpretive judgment by the consulting physician.
 - (3) For reimbursement, the codes must be modified by a 26 (e.g., 8050026) and the claims must be submitted to the department with the attending physician's provider number in the referring physician space on the invoice. When the attending physician's provider number is not available, 911115 must appear in the referring physician space on the invoice and the physician's name and address must appear in the remarks space on the invoice. In addition, the following documentation must be maintained in the patient's medical records and the records of the laboratory (if the laboratory is separate from the physician's office):
 - (a) A copy of the attending physician's request for a consultation;
 - (b) The test results including the identification of any test results that were outside the clinically significant normal or expected range in view of the condition of the patient; and
 - (c) A copy of the written narrative report prepared by the consulting physician.

- (4) The department may recoup payments for a pathology consultation when neither the patient's medical records nor the laboratory records document that the conditions specified in paragraph (G)(3) of this rule have been met.
- (H) Evocative/suppression testing.
- (1) Codes 80400 to 80440 are for the laboratory component of the test (the actual measurement of the chemical constituents) and are reimbursable only to the laboratory that actually performed the laboratory analysis.
 - (2) A provider of physician services may be reimbursed for professional services associated with evocative/suppression testing which include the supervision and monitoring of the patient during testing, the physician's intermittent or continual attendance during the administration of the evocative/suppression drug or agent and the physician's interpretation of the test results as they relate to the patient's condition. Evaluation and management codes may be billed for the same date of services if the physician provided separate and identifiable evaluation and management services to the patient.
 - (3) Reimbursement is available to a provider of physician services for evocative/suppression testing agents administered in a non-hospital setting by billing the appropriate injection codes in accordance with rule 5101:3-4-13 of the Administrative Code. The injection codes include the provision of the drug/chemical agent and the administration of the drug/agent when the drug/agent is administered intradermally, subcutaneously, intramuscularly, intraarterially, or intravenously (via injection, push IV, or an IV infusion of short duration).
 - (4) When the administration of the evocative/suppression agent in a non-hospital setting requires prolonged intravenous infusions the provider may also receive reimbursement for prolonged infusion services by billing codes 90780 and 90781 in addition to the codes for the drug/agent. Reimbursement for these codes include the additional supplies used in the prolonged administration of the drug agent.
- (I) Billing the laboratory procedure codes.
- (1) The provider must assign the most appropriate code for each laboratory procedure performed. Some procedures are listed by the name of the substance (analyte) being measured; some are listed by methodology (e.g., RIA, EIA, TLC, Culture, etc.); some are listed by both the name and methodology; and some are differentiated by the specimen type (e.g., urine, blood, etc.).
 - (2) The provider must bill the code that describes the procedure in the most detail. Codes using the term "not elsewhere specified" in the definition for the procedure may only be used when the laboratory is performing a quantitative test for a specific analyte for which there is no specific code.
 - (3) Many laboratory procedures, especially procedures for drug level testing, have synonyms. Therefore, the name the laboratory uses for a test may not be the same name used in the. When a synonym for a laboratory procedure exists, the provider must bill using the synonymous code.
 - (4) If a suitable procedure is not available for the substance (analyte) or method, the provider must bill the miscellaneous or unlisted laboratory procedure code listed under the laboratory specialty for the procedure. These codes must be billed "by report."
 - (a) When billing the unlisted laboratory procedure codes, the name of the substance being measured, the specimen type, and the methodology must be written in the remarks column of the claim form.
 - (b) Claims omitting this information or billing the unlisted codes when a code is available may be denied by the department.
- (J) Reimbursement for neonatal diagnostic screening kits.

- (1) A "neonatal diagnostic screen kit" is a laboratory kit used for screening neonates for phenylketonuria, homocystinuria, galactosemia, hypothyroidism, or other genetic endocrine or metabolic disorders.
 - (2) Reimbursement for neonatal diagnostic screening kits which are purchased from the Ohio department of health state laboratory is allowable to the physician, hospital, or clinic if one of the following circumstances applies:
 - (a) The screen was performed for the first time because the infant was not born in a hospital and was never admitted to the hospital; or
 - (b) The screen was repeated because the infant was released from the hospital prior to reaching forty eight hours of age; or
 - (c) The screen was repeated because the original screen of the infant showed an abnormal result and the infant is no longer an inpatient of the hospital.
 - (3) The department will recognize code S3620 for the reimbursement of the neonatal diagnostic screen kit.
- (K) Non-covered laboratory services.
- (1) The following laboratory services are non-covered under medicaid:
 - (a) Laboratory services exceeding the coverage and limitations set forth in Chapter 5101:3-11 of the Administrative Code;
 - (b) Routine laboratory and screening procedures;
 - (c) Laboratory services performed in conjunction with non-covered physician services as defined in rule 5101:3-4-28 of the Administrative Code;
 - (d) Laboratory services performed for forensic reasons;
 - (e) Paternity testing; and
 - (f) Laboratory procedures performed in conjunction with an autopsy.
 - (2) The recipient's liability for non-covered laboratory services is detailed in rule 5101:3-1-13.1 of the Administrative Code. In addition, the recipient may not be billed for any laboratory procedures performed by a laboratory that is not certified to perform the procedure under CLIA.

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MAL 501

Effective Date: May 5, 2006

Most Current Prior Effective Date: March 31, 1999

(A) Definitions.

For the purpose of this rule:

- (1) "Facility" means any federally qualified health center (FQHC), rural health center (RHC), or outpatient health facility (OHF) ~~which~~ that has signed an Ohio medicaid "provider agreement."
- (2) A facility shall be considered "related to" another facility if one facility owns the other facility or the two facilities are owned by the same (separate) entity.
- (3) A "~~Hospital~~ hospital provider" is a hospital eligible for participation in the medicaid program in accordance with rule 5101:3-2-01 of the Administrative Code.
- (4) "Clinical Laboratory Improvement Amendment" (CLIA) sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens.

(B) ~~FQHCS, RHCS, OHFS,~~ FQHCs, RHCs, OHFs or the combination of any of the three may bill for laboratory procedures they do not actually perform if:

- (1) The procedures were referred to and performed by a facility that is related to the referring FQHC, RHC, or OHF;
- (2) The (reference) facility that actually performed the procedures is certified to perform the service under the clinical laboratory improvement amendments (CLIA);
- (3) The referring facility discloses, in writing to the department, the following information:
 - (a) The name, address, and CLIA number of the reference facility;
 - (b) Information on the ownership of and/or relationship between the referring facility and the reference facility; and
 - (c) A list of the laboratory procedures referred to the reference facility.
- (4) The referring facility must notify the department in writing of any changes made to the disclosure information specified in paragraph (B)(3) of this rule.
- (5) The department will exclude from the cost reports any costs allocated for laboratory procedures performed by facilities or laboratories ~~which~~ that are not certified to perform the procedures under CLIA.

(C) For hospital outpatients, hospital providers may bill for clinical laboratory procedures they do not actually perform, when the procedures are referred to and performed by a laboratory that is certified to perform the service under the ~~Clinical Laboratory Improvement Amendments (CLIA).~~

- (1) When clinical laboratory services for hospital outpatients are performed by a reference laboratory, the referring hospital provider must have a written arrangement with the reference laboratory that specifies which provider will bill the department for the laboratory services. If the hospital provider bills for a clinical laboratory service performed by a reference laboratory, the reference laboratory must not bill either medicaid or the beneficiary for its service. If the reference laboratory bills for the clinical laboratory service, the referring hospital must not bill either medicaid or the beneficiary for the service.
- (2) In the event that the department issues payment to both the referring hospital and the reference laboratory for the same clinical laboratory service, the department will make the assumption that the payment issued to the reference laboratory is subject to recovery.

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MAL 501

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Most Current Prior Effective Date: August 1, 2001

- (A) Providers may not bill the department for procedures performed by the Ohio department of health (ODH) state laboratory.
- (B) All Ohio medicaid providers who wish to utilize the ODH state laboratory for laboratory tests performed for medicaid ~~recipients~~ consumers must:
 - (1) Complete the top portion of the HCFACMS 1500 claim form (rev. September 2003), for each ~~recipient~~ consumer (i.e., ~~recipient~~ consumer information only).
 - (2) Include the HCFACMS 1500 claim form along with all other attachments required by ODH in the package with the specimen and submit to ODH.
 - (3) Not attach the prepaid stamp ~~which~~ that ODH normally requires before the test is performed.
- (C) The ODH state laboratory will complete the HCFACMS 1500 claim form and submit the claim for payment.

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MAL 501

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- (A) Portable x-ray services are limited to the following radiology services:
- (1) Skeletal films involving the extremities, pelvis, vertebral column, and skull;
 - (2) Chest films ~~which~~ that do not involve the use of contrast media;
 - (3) Abdominal films ~~which~~ that do not involve the use of contrast media and;
 - (4) Diagnostic mammograms if the provider meets the requirements in 21 ~~CFR~~ C.F.R. (April 1, 2005) part 900 subpart B.
- (B) Procedures and examinations that are not covered when provided by a portable x-ray provider include:
- (1) Procedures involving fluoroscopy;
 - (2) Procedures involving the use of contrast media;
 - (3) Procedures requiring the administration of a substance to the patient or the injection of a substance into the patient and/or special manipulation of the patient;
 - (4) Procedures ~~which~~ that require special medical skill or knowledge possessed by a doctor of medicine or doctor of osteopathy, or that require that medical judgment be exercised;
 - (5) Procedures requiring special technical competency and/or special equipment or materials;
 - (6) Routine screening procedures; and
 - (7) Procedures ~~which~~ that are not of a diagnostic nature.
- (C) Reimbursement is available for the transportation of portable x-ray equipment to a patient's home, or to a long-term care facility (LTCF). In a LTCF, only one such charge per visit, to the supplier is allowed, regardless of the number of patients seen.
- (D) For a portable x-ray service to be covered under medicaid:
- (1) The service must be medically necessary as defined under rule 5101:3-1-01 of the Administrative Code; and
 - (2) The service must be requested by a physician in writing.
 - (a) The service may be performed on the verbal request of a physician but the laboratory must obtain a written order dated and signed by the physician before the services may be billed to the department.
 - (b) The physician's order must specify the reason the x-ray is medically necessary and must specify the x-ray procedure(s) to be performed, including the number of radiographs to be obtained and the views needed.
 - (c) ~~Services are~~ The service must be performed under the general supervision of a physician.
- (E) The portable x-ray supplier must keep the following records for each patient for a period of at least six years:
- (1) The date of the x-ray examination;
 - (2) A copy of the written, signed and dated order by the patient's physician;
 - (3) The name of the operator(s) of the portable x-ray equipment; and

- (4) The name of the physician who performed the professional interpretation of the procedure and the date the radiograph was sent to the physician.
- (F) Billing for portable x-ray supplier services.
- (1) Portable x-ray suppliers may bill for the total procedure of a covered x-ray service if the supplier provided both the technical and the professional components of the procedure.
- (a) ~~To~~ For the supplier to be eligible for reimbursement of the total procedure, the professional component must be provided by a qualified physician who either owns, is employed by or is under contract with the portable x-ray supplier.
- (b) To bill for the total procedure of a covered portable x-ray service, the provider must bill the CPT code, in accordance with division-level [5101:3](#) of the Administrative Code, for the procedure without a modifier.
- (2) Portable x-ray suppliers may only bill for the technical component when the supplier performed the technical services and a physician not associated with the supplier by ownership, employment, or contract provided the professional services (e.g., the patient's treating physician interpreted the x-ray procedure).
- To bill for the technical component, the provider must bill the CPT code for the procedure followed by the modifier TC (e.g., 71010TC).
- (3) A portable x-ray supplier may not bill separately for the professional component.

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MAL 501

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Most Current Prior Effective Date: August 1, 2001

- (A) For independent diagnostic testing facility services to be covered:
- (1) The service must be medically necessary as defined in rule 5101:3-1-01 of the Administrative Code; and
 - (2) The service must be requested in writing by the treating physician or non-physician practitioner in accordance with state law.
 - (a) The service may be performed upon the verbal order of the treating physician but the independent diagnostic testing facility must obtain an order ~~which~~ that is written, dated, and signed by the treating physician before the service is billed to the department.
 - (b) The treating physician's order must specify the procedures to be performed and the reason for the service.
 - (c) A copy of the written, dated, and signed treating physician's order must be kept on file for six years.
 - (d) The independent diagnostic testing facility may not add any procedures based on internal protocols without a written order by the treating physician.
- (B) ~~Covered independent diagnostic testing facility procedures are limited to tests and the specific CPT codes for those tests specified in medicare regulations for independent diagnostic testing facilities.~~ An independent diagnostic test facility may not perform or bill for CLIA tests. An entity that owns both an independent diagnostic testing facility and an independent laboratory should enroll and bill separately to Ohio medicaid.
- (C) Services are reimbursable directly to a independent diagnostic testing facility only if the services were rendered to a nonhospital patient and the independent diagnostic testing facility provided all services (professional and technical) associated with the total procedure as the procedure is defined in the CPT with the following exceptions:
- (1) When separate CPT codes itemize a service by its professional and technical components, the independent diagnostic testing facility may bill and be reimbursed for the components of the procedure it actually performed.
 - (2) When the service provided is an echocardiography or a radiology procedure, the independent diagnostic testing facility may provide, bill and be reimbursed for either the total procedure or for the technical component of the procedure.
 - (a) To bill for the technical component of an echocardiography or a radiology procedure, the independent diagnostic testing facility must bill the CPT code followed by the modifier TC (e.g., 93307TC).
 - (b) To bill for the total procedure, the independent diagnostic testing facility must bill the CPT code without a modifier.
- (D) When an independent diagnostic testing facility provides services for a hospital inpatient, a hospital outpatient, or a hospital emergency room patient, the hospital must bill and be reimbursed for the technical services associated with the procedure and the physician who provided the professional services associated with the procedure must bill for the professional component. The independent diagnostic testing must make separate arrangements to receive payment from the hospital for the services rendered to a hospital patient.

R.C.119.032 review dates: 03/09/2006 and 05/01/2011

Certification: CERTIFIED ELECTRONICALLY

Date: 05/15/2006

Promulgated Under: 119.03

Statutory Authority: 5111.02

Rule Amplifies: 5111.01, 5111.02

Prior Effective Dates: 2/17/91, 8/1/01

***Formerly* 5101:3-11-08 Reimbursement for Laboratory, Portable X-Ray Supplier, and Independent Diagnostic Testing Facilities**

Effective Date: April 1, 2004

- (A) Payment for services is the provider's billed charges or the medicaid maximum payment schedule (sometimes referred to as the medicaid maximum or the fee schedule) as specified in this rule, whichever is lower.
- (B) Medicaid maximum for laboratory services.
- (1) For a laboratory service that is payable under the medicare laboratory fee schedule, the medicaid payment for the service shall not exceed the medicare carrier's laboratory fee schedule for that service.
 - (2) The maximum amount payable for clinical laboratory procedures is specified in appendix DD of rule 5101:3-1-60 of the Administrative Code.
 - (3) The maximum amount payable for the total procedure of an anatomical pathology procedure is specified in rule 5101:3-1-60 of the Administrative Code.
 - (4) The maximum amount payable for the professional component of anatomical pathology procedures is ~~four hundred per cent of the amount specified for the procedure~~ specified by the corresponding professional/technical indicator in appendix DD of rule 5101:3-1-60 of the Administrative Code.
 - (5) The maximum amount payable for the technical component of anatomical pathology procedures is ~~one hundred per cent of the amount specified for the procedure~~ specified by the corresponding professional/technical indicator in appendix DD of rule 5101:3-1-60 of the Administrative Code.
- (C) Medicaid maximum for radiology services.
- (1) The maximum amount payable for the total procedure for a radiology service is specified in rule 5101:3-4-25 of the Administrative Code.
 - (2) The maximum amount payable for the professional component of a radiology service is specified of rule 5101:3-4-25 of the Administrative Code.
 - (3) The maximum amount payable for the technical component of a radiology service is specified in rule 5101:3-4-25 of the Administrative Code.
- (D) Medicaid maximum for other independent diagnostic testing facilities
- For independent diagnostic testing facilities not included in those services referred to in paragraph (C) of this rule:
- (1) The maximum amount payable for those procedures for which the department recognizes professional and technical components is specified in rule 5101:3-4-11 of the Administrative Code.
 - (2) The maximum amount payable for all other procedures is specified in appendix DD of rule 5101:3-1-60 of the Administrative Code.
- (E) Laboratory, radiology, and diagnostic and therapeutic services provided to hospital inpatients.
- (1) The following services furnished to hospital inpatients are covered under the medicaid program as inpatient hospital services and are reimbursed in accordance with provisions governing payment for inpatient services as set forth in Chapter 5101:3-2 of the Administrative Code:
 - (a) Clinical laboratory services;
 - (b) The technical component of anatomical pathology procedures; and
 - (c) The technical component of radiology, and diagnostic and therapeutic services.

- (2) The department will deny separate charges made by providers, or will recoup separate payments made to providers, for services specified in paragraph (E) of this rule which were rendered for hospital inpatients.

Effective: 04/01/2004

R.C. 119.032 review dates: 01/16/2004 and 04/01/2009

Certification: CERTIFIED ELECTRONICALLY

Date: 03/22/2004

Promulgated Under: 119.03

Statutory Authority: 5111.02

Rule Amplifies: 5111.01, 5111.02

Prior Effective Dates: 10-1-84, 10-1-84 (Emer.), 12-30-84, 5-9-86, 2-17-91, 2-1-96 (Emer)., 4-4-96, 8-1-01

5160-11-10 Radiology Procedures that are Subject to the Clinical Laboratory Improvement Amendments (CLIA) Requirements

***Formerly* 5101:3-11-10 Radiology Procedures that are Subject to the Clinical Laboratory Improvement Amendments (CLIA) Requirements**

MAL 496

Effective Date: March 27, 2006

Most Current Prior Effective Date: December 30, 2005 (Emergency)

- (A) Any providers submitting claims for the radiology procedures listed in this rule citing either the technical component only or the technical and professional component combined must be certified under CLIA.
- (B) Any providers submitting claims citing only the performance of the professional component of the radiology procedures listed in this rule are not subject to the requirements under CLIA.

78110	Plasma volume, radionuclide volume-dilution technique; single sampling.
78111	Plasma volume, radionuclide volume-dilution technique; multiple sampling.
78120	Red cell volume determination; single sampling.
78121	Red cell volume determination; multiple sampling.
78122	Red cell volume determination; multiple sampling.
78130	Red cell survival study.
78160	Plasma radioiron disappearance rate.
78162	Radioiron oral absorption.
78191	Platelet survival study.
78270	Vitamin B-12 absorption studies combined, with and without intrinsic factor.
78271	Vitamin B-12 absorption studies combined, with and with intrinsic factor.
78272	Vitamin B-12 absorption studies combined, with and without intrinsic factor.

Effective Date: 03/27/2006

R.C. 119.032 review dates: 01/10/2006

Certification

Promulgated Under: 119.03

Statutory Authority: 5111.02

Rule Amplifies: 5111.01, 5111.02

Prior Effective Dates: 7/1/93, 12/31/98 (Emer), 3/31/99, 12/30/05 (Emer)

LAB Appendix

[Billing and general information can be found in the Ohio Medicaid Billing Instructions by clicking here.](#)

Waived Laboratory Procedure Categories

A current list of waived or PPMP lab tests can be found on the CMS web site at <http://www.cms.hhs.gov/CLIA/>

Clinical Laboratory Procedure Codes Allowing Separate Reimbursement for Interpretive Consultations

The [Clinical Laboratory Procedure Codes Allowing Separate Reimbursement for Interpretive Consultations](#) are maintained in the Physician Services Manual, located in the Ohio Health Plans - Provider collection.

Diagnostic and Therapeutic Codes Requiring Modifiers for Billing Components

The [Diagnostic and Therapeutic Codes Requiring Modifiers for Billing Components](#) are maintained in the Physician Services Manual, located in the Ohio Health Plans - Provider collection.

Clinical Procedures and Anatomical Pathology Procedure Codes

The following tables list codes that are considered to be clinical or anatomical pathology procedures. Payable clinical and anatomical pathology procedure codes and their Medicaid maximum reimbursement rate can be found in Appendix DD of rule 5101:3-1-60. To bill for clinical laboratory procedures, the provider must bill the most appropriate code for the procedure (unmodified). Clinical laboratory codes may not be billed with a modifier.

For the purpose of the Medicaid program, the term "anatomical pathology" has been extended to include all laboratory services which require the total involvement or the partial involvement of a physician in the performance of the procedure. The maximum amount payable for the professional and technical component of anatomical pathology procedures is specified by the corresponding professional/technical indicator in appendix DD of rule 5101:3-1-60 of the Administrative Code.

Clinical Procedures

Clinical Procedures		
G0026	85130-86063	88174-88175
Q0111-Q0115	86140-87999	88230-88289, 88299
80048-80090	88130-88155	89050-89060
80100-80440	88164-88167	89125
81000-85055	88230-88299	89160-89399

Anatomical Pathology Procedures

Anatomical Pathology Procedures	
80500-80502	88172-88199
85060-85097	88300-88399
86077-86079	89100-89105
88104-88112	89130-89141
88160-88162	