CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)

Regulation/Package Title: Laboratory-Related Services

Rule Number(s):

To Be Rescinded: 5160-11-02, 5160-11-03, 5160-11-04, 5160-11-06, 5160-11-07, 5160-11-10

New: 5160-11-02, 5160-11-03.1

Date: February 13, 2015

Rule Type:

- ☑ New
- ☐ Amended
- ☑ 5-Year Review
- ☑ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

In accordance with provisions set forth in section 119.032 of the Ohio Revised Code, a systematic review has been made of the nine existing rules in Chapter 5160-11 of the Ohio Administrative Code:

5160-11-01, "Definitions: independent laboratory, portable X-ray supplier, independent diagnostic testing facility (IDTF), and mammography supplier"
5160-11-02, "Provider requirements: independent laboratory, portable X-ray supplier, independent diagnostic testing facility (IDTF), mammography supplier, and other providers of laboratory services"
5160-11-03, "Laboratory services: coverage and limitations"
5160-11-04, "Laboratory: exceptions for FQHCs, RHCs, OHFs, and hospital outpatients"
5160-11-05, "Laboratory specimens sent to the Ohio Department of Health (ODH) state laboratories"
5160-11-06, "Portable X-ray suppliers: covered services and limitations"
5160-11-07, "Independent diagnostic testing facility: coverage and limitations"
5160-11-08, "Reimbursement for laboratory, portable X-ray supplier, and independent diagnostic testing facilities"
5160-11-10, "Radiology procedures that are subject to the Clinical Laboratory Improvement Amendments (CLIA) requirements"

These rules are being rescinded and replaced with six new rules:

5160-11-01, "Laboratory-related services: definitions and explanations"
5160-11-02, "Laboratory-related services: general provisions"
5160-11-03.1, "Laboratory-related services: provisions specific to laboratory procedures"
5160-11-03.2, "Laboratory-related services: provisions specific to portable X-ray services"
5160-11-03.3, "Laboratory-related services: provisions specific to independent diagnostic testing facility (IDTF) services"
5160-11-09, "Laboratory-related services: claim payment"

Six of the rescinded rules (5160-11-02, 5160-11-03, 5160-11-04, 5160-11-06, 5160-11-07, and 5160-11-10) and two of the new rules (5160-11-02 and 5160-11-03.1) potentially could have an adverse impact on business. The scope of this analysis is therefore limited to these eight rules.

Most of the revisions involve improvements in organization of the chapter, structure of the individual rules, and clarity of phrasing. A few specific revisions are worth noting:

- In keeping with recent advances in technology and policies adopted by the Centers for Medicare and Medicaid Services (CMS), the phrase "dated and signed by the physician" (rescinded rules 5160-11-06 and 5160-11-07) has been removed from the description of a written order because it could be misinterpreted to require handwriting. Many forms are now signed and dated electronically.
- For purposes of payment coordination and program integrity, a provision is added that explicitly requires a portable X-ray supplier to be enrolled in Medicare as a supplier of portable X-ray services (new rule 5160-11-02).

- Currently, a written order for a portable X-ray service or for a procedure performed by an independent diagnostic testing facility (IDTF) must include a reason for the service or procedure (rescinded rule 5160-11-07). The revised policy will instead require that at least one appropriate diagnosis code be included on all written orders (new rule 5160-11-02), because a diagnosis code is generally easier to provide than a narrative and imparts just as much information.
- Currently, laboratory providers may submit claims only for those clinical diagnostic laboratory procedures they actually perform, but an exception is made for federally-qualified health centers (FQHCs), rural health clinics (RHCs), and outpatient health facilities (OHFs) that meet certain conditions (rescinded rule 5160-11-04). The revised policy extends this exception to all laboratory providers when the reference laboratory provider is a hospital and the referring laboratory provider is wholly owned by the reference laboratory provider, the reference laboratory provider is wholly owned by the referring laboratory provider, or both of them are wholly owned by a third entity (new rule 5160-11-03.1).
- The taking of a urine sample by catheterization (rescinded rule 5160-11-03) is excluded from the handful of specimen collection procedures that are treated as laboratory-related services. Catheterization is really a physician service, and almost no laboratory providers submit claims for this procedure.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   The Ohio Department of Medicaid (ODM) is promulgating these rules under section 5164.02 of the Ohio Revised Code.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   Under provisions of the Social Security Act, laboratory testing, portable X-ray imaging, and other diagnostic imaging are mandatory Medicaid services. The proposed changes in the rules are not necessitated by federal law; they are being made to improve administration of the Medicaid benefit.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   These rules do not exceed federal requirements.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Medicaid rules perform several core business functions: They establish and update coverage and payment policies for medical goods and services. They set limits on the types of entities that can receive Medicaid payment for these goods and services. They publish

payment formulas or fee schedules for the use of providers and the general public. No alternative is readily apparent.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the rule changes will be measured by the extent to which operational updates to the Medicaid Information Technology System (MITS) result in the correct payment of claims.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   There are no provider associations representing laboratories, IDTFs, mammography suppliers, or portable X-ray suppliers. Medicaid staff members relied on the Ohio Hospital Association (OHA) and two large providers of laboratory services to review the most significant of the changes in the proposed rules, including the allowance of claim submission by related entities for providers other than cost-based clinics.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

   OHA actually suggested the expansion of the claim-submission provision to alleviate a problem faced by one of its members.

   From 10/20/2014 through 11/03/2014, these rules were made available for public comment through a process known as Clearance. No comments were submitted.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

   Any needed utilization or expenditure data pertaining to urine sampling by catheterization were drawn from ODM's Quality Decision Support System.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    Three of the major changes—explicitly requiring a portable X-ray supplier to be enrolled in Medicare, requiring a diagnosis code in lieu of a written narrative, allowing claim submission by related entities for providers other than cost-based clinics—impose or remove restrictions on how a provider interacts with Medicaid.

The Medicare enrollment provision is being added for purposes of payment coordination, program integrity, and consistency (in that a similar requirement already exists for IDTFs and, by extension, mammography suppliers). Because of the likelihood that portable X-ray suppliers enrolled in Medicaid are also enrolled in Medicare, the functional effect of the provision is to simplify enrollment for portable X-ray suppliers through the establishment of a single set of qualifying criteria.

The changes involving specification of a diagnosis code and claim submission by related entities are being made specifically to remove obstacles for providers. The alternative—leaving the existing provisions intact—was determined not to be acceptable.

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-*based regulations define the required outcome, but don't dictate the process* the regulated stakeholders must use to achieve compliance.

The concept of performance-based rule-making does not apply to these services.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Rules involving Medicaid providers are housed exclusively within agency 5160 of the Ohio Administrative Code. Within this division, rules are generally separated out by topic. It is clear which rules apply to which type of provider and item or service; in this instance, there was no duplication.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The policy changes will be incorporated into (1) internal Medicaid processes and (2) the Medicaid Information Technology System (MITS), which is the department's electronic claim-payment system. Incorporation into ODM processes and systems will ensure that the rules are applied consistently and predictably.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

c. Quantify the expected adverse impact from the regulation. The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

These rules affect laboratories, independent diagnostic testing facilities (IDTFs), mammography suppliers, and portable X-ray suppliers.

As a condition of Medicaid participation, these rules require compliance with various provisions of federal law. Clinical laboratories, for example, must have certification compliant with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This federal requirement applies to all laboratories doing testing on human subjects, so its use as a Medicaid provider enrollment requirement can be expected to have no adverse impact.

The provision that portable X-ray suppliers, like IDTFs, must be enrolled in Medicare is being implemented for purposes of payment coordination and program integrity. Most if not all portable X-ray suppliers and IDTFs already participate in Medicare, so this Medicaid provider enrollment requirement can be expected to have no adverse impact.

Provisions in these rules that govern IDTFs set forth requirements not only for compliance with federal law and enrollment in Medicare but also for the periodic submission of statements about supervising physicians and the maintenance of procedure and quality control manuals. Each statement simply confirms the existence of a business relationship between the IDTF and a supervising physician, and keeping current operations manuals is a standard business practice, so the adverse impact resulting from these aspects of the rules can be expected to be negligible.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Requiring a diagnosis code in lieu of a written narrative and allowing claim submission by related entities for providers other than cost-based clinics are expected to have a positive impact on providers.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Provider enrollment requirements are not predicated on the size of an entity and cannot be waived on that basis.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The rules impose no fines or penalties.

18. What resources are available to assist small businesses with compliance of the regulation?

Providers that submit claims through an electronic clearinghouse (a "trading partner") can generally rely on the clearinghouse to know current Medicaid claim-submission procedures.

Information sheets and instruction manuals on various claim-related topics are readily available on the Medicaid website.

Policy questions may be directed via e-mail to the Non-Institutional Benefit Management section of ODM's policy bureau, at noninstitutional_policy@medicaid.ohio.gov.

TO BE RESCINDED

5160-11-02 **Provider requirements: independent laboratory, portable x-ray supplier, independent diagnostic testing facility (IDTF), mammography supplier, and other providers of laboratory services.**

(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).

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5162.03, 5164.02, 5164.70
Prior Effective Dates:	04/07/1977, 09/19/1977, 12/21/1977, 12/30/1977, 10/01/1984 (Emer), 12/30/1984, 05/09/1986, 06/01/1986, 02/17/1991, 09/02/1992 (Emer), 12/01/1992, 04/30/1993 (Emer), 07/01/1993, 08/01/2001, 02/01/2003, 06/01/2009

TO BE RESCINDED

5160-11-03 **Laboratory services: coverage and limitations.**

(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)

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, 9111115 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, galactomsemia, 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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Laboratory Services

CODE	DEFINITION
83020	Hemogolbin electrophorisis
83912	Nucleic acid probe, with electrophoresis, exam and report
84165	Protein, total serum; electrophorectic fractionization and quantitation
84166	Protein electrophoretic fraction quart
84181	Western blot
84182	Western blot, immunologic probe
85390	Fibrinolysin; screening
85396	Fibrinolysin; screening
85576	Platelet aggregation (In Vitro), any agent
86255	Fluorescent antibody; screen
86256	Fluorescent antibody; titer
86320	Immunoelectrophoresis; each specimen
86325	Immunoelectrophoresis; other fluids with concentration, each specimen
86327	Immunoelectrophoresis, crossed (2-D)
86334	Immunofixation electrophoresis
86335	Immunofix electrophresis fluid w/concern
87164	Darkfield examination, any source; includes specimen collection
87207	Smear; primary source, with interpretation; special stain for inclusion bodies or intracellular parasites
89060	Crystal ID by light microscopy w/wo polar lens; any fluid not urine
88245	Chromosome analysis
88248	Chromosome analysis
88261	Chromosome analysis
88262	Chromosome analysis
88263	Chromosome analysis
88267	Chromosome analysis
88269	Chromosome analysis
88280	Chromosome analysis
88283	Chromosome analysis
88285	Chromosome analysis
88289	Chromosome analysis
88299	Chromosome analysis

TO BE RESCINDED

5160-11-04 **Laboratory: exceptions for FQHCs, RHCs, OHFs, and hospital outpatients.**

(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) 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 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 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 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 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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TO BE RESCINDED

5160-11-06 **Portable x-ray suppliers: covered services and limitations.**

(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 that do not involve the use of contrast media;

(3) Abdominal films that do not involve the use of contrast media and;

(4) Diagnostic mammograms if the provider meets the requirements in 21 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 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 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) 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) 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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TO BE RESCINDED

5160-11-07 **Independent diagnostic testing facility: coverage and limitations.**

(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 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) 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.

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TO BE RESCINDED

5160-11-10 **Radiology procedures that are subject to the clinical laboratory improvement amendments (CLIA) requirements.**

(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.
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.

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5160-11-02 **Laboratory-related services: general provisions.**

(A) A specialized provider of laboratory services must fulfill specific requirements.

(1) An independent laboratory must meet the following criteria:

(a) It must meet all the applicable standards of compliance listed at 42 C.F.R. 493.3 (October 1, 2014).

(b) It must perform procedures that are appropriate to its level of certification under CLIA.

(i) A provider possessing only a certificate of waiver may receive payment only for waived procedures.

(ii) A provider possessing only a certificate for provider-performed microscopy (PPM) procedures may receive payment only for waived and PPM procedures.

(iii) A provider possessing a certificate of registration, a certificate of compliance, or a certificate of accreditation may receive payment for the following procedures:

(a) Waived procedures;

(b) PPM procedures;

(c) Tests of moderate complexity, if the provider fulfills the applicable requirements set forth in 42 C.F.R. 493.20 (October 1, 2014); and

(d) Tests of high complexity, if the provider fulfills the applicable requirements set forth in 42 C.F.R. 493.25 (October 1, 2014).

(2) A portable x-ray supplier must meet the following criteria:

(a) It must comply with the conditions set forth in 42 C.F.R. part 486 subpart C (October 1, 2014).

(b) It must be enrolled in medicare as a supplier of portable x-ray services.

(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 (October 1, 2014).

(b) It must be enrolled in medicare as an 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 works for the facility either as an employee (full-time or part-time) or under contract and has responsibilities that 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 rule 5160-1-17.2 of the Administrative Code.

(4) A mammography supplier must meet the following criteria:

(a) It must participate in medicaid as an IDTF.

(b) It must comply with the conditions set forth in 42 C.F.R. 410.34 (October 1, 2014).

(B) Payment can be made for a laboratory-related service only if all of the following conditions are satisfied:

(1) The procedure is medically necessary in accordance with Chapter 5160-1 of the Administrative Code, or the procedure is medically indicated when performed in conjunction with a covered preventive health service defined in Chapter 5160-4 of the Administrative Code.

(2) Although the service may be rendered on the verbal order of a qualified practitioner, the laboratory provider must obtain a written order before submitting a claim.

(a) A written order may consist of an entry in a person's medical records (e.g., in an individual physician's office, a group practice, a clinic, or a hospital).

(b) A necessary follow-up procedure (e.g., a quantitative test performed in response to a positive qualitative test result) does not require a separate written order so long as the procedure follows appropriate standard practices and is included in the laboratory provider's written protocols. A laboratory provider, however, must not submit a claim for any additional procedure that is based solely on internal protocols without first obtaining a written order.

(3) A written order must include the following information:

(a) The name of the medicaid-eligible individual;

(b) Contact information for the practitioner ordering the service;

(c) Specification of the service (e.g., procedure code, description, number of units);

(d) At least one appropriate diagnosis code;

(e) The date of the order;

(f) The names of the relevant persons or entities involved in providing the service (e.g., referring laboratory, reference laboratory, interpreting practitioner, radiographer); and

(g) Any additional information necessary to ensure accurate and timely testing or reporting (e.g., for a Pap test, the beginning date of the individual's last menstrual period, her age or date of birth, an indication of previous abnormal results and subsequent actions).

(4) A laboratory provider must keep a copy of each written order for the period of time specified in rule 5160-1-17.2 of the Administrative Code and must make it available to the department on request.

(C) Certain laboratory-related services are excluded from medicaid payment.

(1) In general, no payment is made for the following services:

(a) Laboratory-related services exceeding the provisions set forth in this chapter;

(b) Routine laboratory or screening procedures;

(c) Laboratory-related services requiring CLIA certification for which a laboratory provider is not appropriately certified under CLIA;

(d) Laboratory-related services rendered in conjunction with non-covered services, which are delineated in rule 5160-1-61 of the Administrative Code; and

(e) Laboratory-related services rendered for forensic investigation, autopsy, or paternity testing.

(2) Although certain provisions in Chapter 5160-1 of the Administrative Code allow an eligible provider to seek payment directly from a medicaid-eligible individual for services that are not covered by the medicaid program, no laboratory provider may seek payment for any laboratory-related service for which it lacks the necessary CLIA certification.

(D) Payment is made in accordance with Chapter 5160-2 of the Administrative Code for the following services, which in a hospital setting are treated not as laboratory-related services but rather as hospital services:

(1) Clinical diagnostic procedures performed for hospital inpatients;

(2) The technical component of physician pathology procedures performed for hospital inpatients; and

(3) The technical component of other laboratory-related services performed for hospital patients.

(E) Payment may be made to a qualified practitioner or a clinic only for the following laboratory-related services:

(1) A clinical diagnostic procedure or specimen collection actually performed in the practitioner's office, group practice, or clinic;

(2) The professional component of a physician pathology procedure or other laboratory-related service;

(3) A global physician pathology procedure if the following conditions are satisfied:

(a) The practitioner operates a full-service, in-office laboratory certified for the performance of the technical component; and

(b) The procedure was not performed for a hospital patient;

(4) A clinical pathology consultative service; or

(5) The professional administration of a testing device, isotope, or other material.

(F) When submitting a claim to the department, laboratory providers must use the code that describes the procedure in the most detail.

(1) Analytic procedures can be listed by analyte (the substance or material being measured), by method, by both analyte and method, or by specimen type (e.g., urine, blood). Many laboratory procedures, especially drug tests, have synonyms. Care must therefore be taken in the selection of the most appropriate procedure code.

(2) A "not otherwise specified," "miscellaneous," or "unlisted" procedure code in the appropriate area of specialty may be used only if no other code accurately corresponds to a procedure. The laboratory provider must submit a claim for such a service "by report" in accordance with rule 5160-4-02.1 of the Administrative Code. The analyte, the specimen type, and the method must be noted in the claim. The department may deny a claim that omits necessary information or that includes a "not otherwise specified," "miscellaneous," or "unlisted" procedure code when an appropriate procedure-specific code is available.

Replaces: 5160-11-02, part of 5160-11-03, part of 5160-11-06, part of 5160-11-07, part of 5160-11-08

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5160-11-03.1 **Laboratory-related services: provisions specific to laboratory procedures.**

(A) Referral.

(1) In general, payment for a clinical diagnostic procedure may be made only to the laboratory provider that actually performs the procedure. Payment may be made to a referring provider for a clinical diagnostic procedure performed by a reference laboratory only if all of the following conditions are satisfied:

(a) The reference laboratory has the appropriate CLIA certification to perform the procedure;

(b) One of the following two sets of criteria is met:

(i) Either the referring provider is a cost-based clinic or the reference laboratory is a hospital, and the referring provider and the reference laboratory are related in one of three ways:

(a) The referring provider is wholly owned by the reference laboratory;

(b) The reference laboratory is wholly owned by the referring provider; or

(c) Both of them are wholly owned by a third entity; or

(ii) The referring laboratory is a hospital that performs clinical diagnostic procedures, the procedure is performed for a hospital outpatient or hospital emergency department patient, and the referring laboratory provider and the reference laboratory provider have a written agreement that specifies which provider is exclusively permitted to submit claims to the department for clinical diagnostic procedures; and

(c) The referring provider discloses to the department in writing the following information and any changes made to it:

(i) The name, address, and CLIA number of the reference laboratory;

(ii) A delineation of the relationship between the referring provider and the reference laboratory; and

(iii) A list of all the clinical diagnostic procedures it refers to the reference laboratory.

(2) In the event that the department issues payment to both a referring provider and a reference laboratory for the same clinical diagnostic procedure, the assumption is made that the payment issued to the reference laboratory is subject to recovery.

(B) Payment for procedures bundled into a panel.

(1) When a provider performs all of the constituent procedures of a covered panel, the provider must submit a claim for the panel rather than for each constituent procedure separately.

(2) The provider must not define a panel differently than does the CPT, and all of the constituent procedures must be medically necessary or medically indicated.

(3) When a provider performs some but not all of the constituent procedures of a panel, the provider must submit a claim for the constituent procedures separately.

(4) When a provider performs more procedures than are included in a panel, the provider may submit a claim for the additional procedures separately.

(C) Payment for clinical consultation or clinical pathology interpretation.

(1) Clinical consultation and clinical pathology interpretation are exclusively professional services and must therefore be performed by a qualified practitioner, usually a pathologist or a hematologist.

(2) A clinical consultation or a clinical pathology interpretation must satisfy the following conditions:

(a) It must be performed for the appropriate procedure.

(i) A clinical consultation may be performed for any clinical diagnostic procedure whose result lies outside the clinically significant normal or expected range for the person's condition.

(ii) A clinical pathology interpretation may be performed only for a clinical diagnostic procedure for which separate payment may be made for interpretation.

(b) It must be ordered in writing by an individual's attending or treating practitioner.

(c) It must require interpretive medical judgment by the consulting or interpreting practitioner.

(d) It must result in a written narrative report prepared by the consulting or interpreting practitioner.

(3) The following documentation must be maintained in the individual's medical records and also in the records of the laboratory if the laboratory is separate from the practitioner's office:

(a) A copy of the referring practitioner's written order for a consultation or an interpretation;

(b) A copy of the clinical diagnostic procedure result for which consultation or interpretation was ordered; and

(c) A copy of the written narrative report prepared by the consulting or interpreting practitioner.

(4) The department may recover payment for a clinical consultation or clinical pathology interpretation if neither the individual's medical records nor the records of the laboratory include the required documentation.

(D) Payment for specimen collection.

(1) Specimen collection performed in a long-term care facility is not a laboratory-related service.

(2) Payment as laboratory-related services may be made only for the following collection procedures:

(a) Collection of a blood specimen by venipuncture;

(b) Collection of a blood specimen by capillary puncture that has the same diagnostic value as a specimen collected by venipuncture;

(c) Collection of a blood specimen from a completely implantable venous access device; and

(d) Collection of a blood specimen from an established central or peripheral venous catheter.

(3) The collection of multiple specimens is considered to be a single procedure in either of the following circumstances:

(a) The specimens are collected in a single encounter from a single body site; or

(b) The specimens are required for a single test (e.g., a glucose tolerance test).

(4) Only the laboratory provider performing a specimen collection may receive payment for it.

(5) Payment for specimen collection includes costs for handling and shipping.

(6) Payment for specimen collection is independent of payment for the laboratory procedure performed on the specimen.

(7) No payment is made for the following collection services:

(a) Collection of a blood specimen by capillary puncture when the collection is part of a test procedure (e.g., bleeding time);

(b) Collection of a specimen for a Papanicolaou test (Pap test, Pap smear) or of a tissue specimen for which there is no discrete procedure code; and

(c) Travel associated with the collection of specimens.

(E) Payment for evocation/suppression testing.

(1) Only the laboratory provider performing the technical evocation/suppression test (the actual measurement of the chemical constituents) may receive payment for it.

(2) Separate payment may be made to a qualified practitioner for identifiable evaluation and management services rendered on the same date of service as an evocation/suppression test. Such services include supervision and monitoring of the individual during testing, intermittent or continual attendance during the administration of the evocation/suppression agent, and interpretation of the test results in relation to the individual's condition.

(3) Separate payment may be made in accordance with Chapter 5160-4 of the Administrative Code for an evocation/suppression testing agent administered to an individual who is not a hospital patient. Such payment includes costs for the agent itself and for administration of the agent, which may be intradermal, subcutaneous, intramuscular, intraarterial, or intravenous (injection by syringe, intravenous push injection, or intravenous infusion of short duration).

(4) Separate payment may be made to a qualified practitioner for prolonged infusion services rendered for an individual who is not a hospital patient. Such payment includes costs for additional supplies used in the prolonged administration of the evocation/suppression testing agent.

(F) Payment for neonatal diagnostic screening.

Payment for neonatal diagnostic screening may be made to a physician laboratory

provider, a hospital laboratory provider, or a clinic laboratory provider if both of the following conditions are satisfied:

(1) The procedure was performed with a kit purchased from the Ohio department of health (ODH) laboratory; and

(2) The kit was used for an initial screening, a repeat screening, or a follow-up screening in accordance with Chapter 3701-55 of the Administrative Code.

Replaces: Part of 5160-11-03, 5160-11-04

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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