Ohio | Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid (ODM)

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Laboratory, Portable X-Ray Supplier, and IDTF Services

Rule Number(s):

SUBJECT TO BUSINESS IMPACT ANALYSIS:

To Be Rescinded: 5160-11-02, 5160-11-03.1

New: 5160-11-11, 5160-11-31

NOT SUBJECT TO BUSINESS IMPACT ANALYSIS, INCLUDED FOR INFORMATION ONLY:

To Be Rescinded: 5160-11-01, 5160-11-03.2, 5160-11-03.3, 5160-11-09

New: 5160-11-21

Date of Submission for CSI Review: 09/10/2020

Public Comment Period End Date: 09/17/2020

Rule Type/Number of Rules:

New/_2_ rules

No Change/____ rules (FYR? ___)

Amended/____ rules (FYR? ___)

Rescinded/__2_ rules (FYR? _2_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **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 106.03 of the Ohio Revised Code, a systematic review has been made of the six existing rules in Chapter 5160-11 of the Ohio Administrative Code:

   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"

   These six rules are being rescinded and their provisions incorporated into three new rules:

   5160-11-11, "Laboratory services"
   5160-11-21, "Portable x-ray supplier services"
   5160-11-31, "Independent diagnostic testing facility (IDTF) services"

Two of the rescinded rules (5160-11-02 and 5160-11-03.1) and two new rules (5160-11-11 and 5160-11-31) potentially could have an adverse impact on business. The scope of this analysis is therefore limited to these four rules.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

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

4. **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.

5. **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 include any provisions that exceed federal requirements.

6. **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)?**

   These rules involve the coverage of and payment for laboratory testing, portable X-ray imaging, and other diagnostic imaging.

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

   The success of these rules will be measured by the extent to which providers can submit claims and receive correct payment.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. 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.

Because of the types of services addressed in OAC Chapter 5160-11, ODM staff members relied on the Ohio Hospital Association (OHA) and two large providers of laboratory services to review the proposed rules. Behavioral health stakeholders and Medicaid managed care plans (MCPs) were also consulted in the development of the policies. E-mail messages with the rules attached were sent on 07/19/2019.

The American Clinical Laboratory Association (ACLA) and Quest Diagnostics submitted similar comments on the proposed rules.

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

Both ACLA and Quest expressed concern over retention of the provision that sets the Medicaid maximum payment amount for a laboratory test at 75% of the corresponding Medicare allowed amount. Ohio Department of Medicaid (ODM) policy staff members thoroughly analyzed the possibility of increasing this percentage from 75% to 80%. Within the constraints of the recently passed biennial state budget, however, no increase was possible.

In response to another comment made by Quest Diagnostics, the wording of the section concerning bundled procedures was expanded to specify two national authorities (the AMA and CMS) that define which constituent procedures are included in a panel.

11. 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?

Fiscal impact data were drawn from ODM's Quality Decision Support System.

12. 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?

Policy governing the Medicaid program can be explained, clarified, and emphasized through means such as advisory letters and training sessions, but it is established in administrative rule. ODM is statutorily required to adopt rules to establish coverage of Medicaid services and payment for those services. Rules governing services provided by laboratories, portable X-ray suppliers, IDTFs, and mammography suppliers are set forth in OAC Chapter 5160-11.

13. 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 rules.

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

In the process of incorporating existing rule text into the new rules, ODM staff members took great care not to duplicate provisions. Any provision of another rule that applies specifically to these services is incorporated by reference.

15. 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 set forth in these rules 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.

16. 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; and

b. Identify the nature of all adverse impact (e.g., 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.

The rules addressed in this analysis (rescinded rules 5160-11-02 and 5160-11-03.1 and new rules 5160-11-11 and 5160-11-31) affect laboratories, portable X-ray suppliers, independent diagnostic testing facilities (IDTFs), and mammography suppliers enrolled in the Ohio Medicaid program.

Clinical laboratories must have certification compliant with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA certification is a federal requirement and a defining characteristic of laboratory providers, which is why it is included in the Medicaid rules. But because this federal requirement applies to all laboratories doing testing on human subjects, any associated adverse impact cannot be attributed solely to these Medicaid rules.

In general, payment for a clinical diagnostic procedure may be made only to the laboratory provider that actually performs the procedure. When a referring provider meeting certain criteria seeks payment for clinical diagnostic procedures performed by a reference laboratory, ODM may request some basic information: the identity of

the reference laboratory; a delineation of the relationship, and a list of all the clinical diagnostic procedures routinely referred. Such a one-time, one-page communication is a standard business activity, the cost of which is minimal.

As a condition of Medicaid participation, the rescinded rules require portable X-ray suppliers and IDTFs to be enrolled simultaneously in Medicare. This enrollment requirement articulates the intent of Medicaid to simplify certification and to allocate responsibility for payment. By the nature of the industry or by law, however, these providers already participate in Medicare; therefore, any adverse impact of Medicare enrollment cannot be attributed to these Medicaid rules. The enrollment requirement is redundant and has been omitted from the new rules.

One provision in these rules requires periodic attestation by supervising practitioners of their role in an IDTF. Each attestation statement simply confirms the existence of a business relationship between the IDTF and a supervising practitioner. Including attestation statements in an enrollment or re-enrollment package involves a negligible amount of additional time, effort, and cost.

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

Clinical laboratories must have the appropriate CLIA certification to perform and receive payment for laboratory services provided. This CLIA certification is a federal requirement; the Ohio Medicaid rules are required to follow this federal requirement and do not add any additional adverse impact. The requirements that portable X-ray suppliers and IDTFs be enrolled in Medicare and that supervising practitioners in IDTFs attest to their roles were implemented for purposes of payment coordination and program integrity.

Regulatory Flexibility

18. 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.

19. 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?

These rules impose no sanctions on providers.

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

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 Policy section of ODM's policy bureau, at noninstitutional_policy@medicaid.ohio.gov.

TO BE RESCINDED

5160-11-01 **Laboratory-related services: definitions and explanations.**

(A) The following definitions apply to this chapter.

(1) "CLIA" is an abbreviation for the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578; 42 U.S.C. 263a, as in effect on December 1, 2014).

(2) "Clinical consultation" is the formal evaluation by a qualified practitioner, performed on the written order of a treating practitioner, of test results that appear to be abnormal. Payment for the clinical consultation is based on the physician fee schedule relative value file published by the centers for medicare and medicaid services (CMS). (The procedure code used for clinical consultation is different and separate from the procedure code for the test whose results are being evaluated.)

(3) "Clinical pathology interpretation" is the interpretation, performed on the written order of a treating practitioner by another practitioner, of the results of any of a certain group of clinical diagnostic procedures that are distinguished by three shared traits:

(a) Separate payment may be made for interpretation;

(b) Payment for the clinical diagnostic procedures themselves is based on the clinical laboratory fee schedule published by CMS; and

(c) Payment for the clinical pathology interpretation is based on the physician fee schedule relative value file published by CMS. (The procedure code for the clinical pathology interpretation consists of a professional component modifier appended to the relevant clinical diagnostic procedure code.)

(4) "Cost-based clinic" is a collective term for a federally qualified health center, an outpatient health facility, or a rural health clinic.

(5) "Current procedural terminology (CPT)" is a uniform numeric code set maintained by the American medical association (AMA) that is used primarily to report medical procedures and services.

(6) "Global procedure" is a procedure, in its entirety, that comprises both a professional component and a technical component.

(7) "Healthcare common procedure coding system (HCPCS)" is a standard code set maintained by CMS that is used for claims processing. Level I of the HCPCS is the set of five-digit CPT codes. Level II of the HCPCS is a standardized set of alphanumeric codes used primarily to report products, supplies, and services not included in the CPT.

(8) "Hospital patient" is a collective term for a hospital inpatient, a hospital outpatient, or a hospital emergency department patient.

(9) "Laboratory-related services" is a collective term encompassing the following procedures:

(a) Laboratory procedures;

(b) Nonroutine specimen collection procedures;

(c) Neonatal diagnostic screening performed with a prefabricated kit;

(d) Diagnostic radiology services (e.g., x-ray procedures, mammography procedures); and

(e) Other diagnostic procedures (e.g., imaging procedures such as MRI or ultrasound, imaging-related procedures such as the placement of catheters or the administration of contrast media, electrocardiography services, electrocardiogram monitoring and analysis, stress tests, sleep studies).

(10) "Neonatal diagnostic screening kit" is a prefabricated laboratory kit used for screening a newborn infant for genetic, endocrine, or metabolic disorders listed in Chapter 3701-55 of the Administrative Code.

(11) "Reference laboratory" is a laboratory that receives a specimen from another laboratory for testing.

(12) "Referring laboratory" is a laboratory that sends a specimen to another laboratory for testing.

(13) "Routine procedure" is a procedure for which no separate payment is made for either of two reasons:

(a) It is very common and is performed only in connection with another procedure (e.g., the collection of a clean-catch urine sample or a throat swab); or

(b) It is included in a treatment protocol for which a composite payment amount has been established (e.g., a specific laboratory test performed for an individual receiving dialysis).

(14) "Written order" is a directive that authorizes the performance of a procedure or service. The order must be produced either in writing or by electronic means.

(B) A provider of laboratory-related services may be either specialized or nonspecialized.

(1) "Specialized provider of laboratory-related services" is a collective term for any of the following providers:

(a) "Independent diagnostic testing facility (IDTF)" is a facility or an entity established for the performance of diagnostic tests that are conducted by licensed or certified nonphysician personnel under appropriate physician supervision. An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is separate from an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. 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 it is represented to other practitioners that both the physician-owners and -directors and the facility are available for the performance of diagnostic tests.

(b) "Independent laboratory" is a laboratory that is separate from 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 is considered to be an independent laboratory if it is represented to other practitioners that both the physician-owners and -directors and the facility are available for the performance of laboratory procedures. Facilities that only collect or prepare specimens or that function only as a mailing service and do not perform testing are not considered to be laboratories.

(c) "Mammography supplier" is a facility or an entity established solely for the provision of mammography services. For claim-payment purposes within medicaid, a mammography supplier is treated as an independent diagnostic testing facility.

(d) "Portable x-ray supplier" is an entity established for the provision of diagnostic x-ray services in an individual's place of residence.

(2) "Nonspecialized provider of laboratory-related services" is a collective term for any of the following providers:

(a) An ambulatory surgery center (ASC);

(b) A cost-based clinic;

(c) A fee-for-service clinic;

(d) A hospital eligible for participation in medicaid in accordance with Chapter 5160-2 of the Administrative Code insofar as it is providing services to outpatients (because clinical diagnostic procedures and the technical components of other laboratory-related services provided to hospital inpatients are paid for in the form of a facility fee under an all-inclusive prospective payment system usually based on diagnosis-related groups, or DRGs);

(e) A physician or physician group practice;

(f) A podiatrist or podiatric group practice; or

(g) Another eligible medicaid provider holding appropriate certification under CLIA to perform laboratory procedures.

(C) For purposes of medicaid, most laboratory procedures are divided into two broad categories.

(1) Clinical diagnostic procedures do not require the specialized skills or knowledge of a physician.

(a) Clinical diagnostic procedures have no separate professional and technical components.

(b) Performance of these procedures generally requires CLIA certification of the laboratory provider.

(c) Payment for these procedures is based on the clinical laboratory fee schedule published by CMS.

(2) Professional procedures require the involvement of a qualified practitioner, usually a pathologist or a hematologist.

(a) Physician pathology procedures have both a professional component and a technical component. In most instances, these components are

distinguished on claims by the inclusion of a modifier along with the procedure code. (The professional and technical components of a few procedures may be represented by separate procedure codes.) The professional component of a physician pathology procedure represents the professional services a practitioner renders in the performance of the procedure. It does not represent the simple reading of test results, which is included in the associated originating service (e.g., office visit or surgery).

(b) Some procedures are exclusively professional in nature and have no technical component.

(c) Only an eligible practitioner or an independent laboratory submitting claims on behalf of its physicians (e.g., physician-owners, staff physicians, or physicians under contract with the laboratory) may receive payment for a professional procedure (or a professional component of a procedure).

(d) Payment for physician pathology procedures and for other professional procedures or components of procedures is based on the physician fee schedule relative value file published by CMS. (There are a very few exclusively technical procedures for which payment is also based on the physician fee schedule relative value file.)

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
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TO BE RESCINDED

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.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

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TO BE RESCINDED

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.

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TO BE RESCINDED

5160-11-03.2 **Laboratory-related services: provisions specific to portable x-ray services.**

(A) Procedures having professional and technical components.

(1) In general, a portable x-ray supplier must perform the technical component of a procedure.

(2) A portable x-ray supplier may receive payment for the technical component alone if it performs only the technical component and the professional component is performed by a qualified practitioner not associated with the portable x-ray supplier by ownership, employment, or contract (e.g., interpretation of an x-ray is performed by an individual's treating practitioner).

(3) A portable x-ray supplier may receive payment for a global procedure if it performs both the professional and the technical components. The professional component must be performed by a qualified practitioner who owns, is employed by, or is under contract with the portable x-ray supplier.

(4) A portable x-ray supplier cannot receive payment for the professional component alone.

(B) Conditions for payment.

(1) For payment purposes, only the following radiology procedures are considered to be portable x-ray services: (a) skeletal films involving the extremities, pelvis, vertebral column, and skull; (b) chest films; (c) abdominal films; and (d) diagnostic mammograms if the provider meets the requirements set forth in 21 C.F.R. part 900 subpart B (April 1, 2014).

(2) No payment is made for the following procedures when they are performed by a portable x-ray supplier:

(a) Procedures involving fluoroscopy;

(b) Procedures involving the use of contrast media;

(c) Procedures requiring the administration of a substance to the individual, the injection of a substance into the individual, or special manipulation of the individual;

(d) Procedures requiring special medical skill or knowledge possessed by a qualified practitioner or the exercise of medical judgment;

(e) Procedures requiring special technical competency or special equipment or materials not ordinarily needed for radiography;

(f) Routine screening procedures; and

(g) Procedures that are not of a diagnostic nature.

(3) Payment is available for the one-way transportation of portable x-ray equipment to a medicaid-eligible individual's place of residence. For each visit, only one equipment transportation charge is allowed, regardless of the number of persons served.

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TO BE RESCINDED

5160-11-03.3 **Laboratory-related services: provisions specific to independent diagnostic testing facility (IDTF) services.**

(A) An independent diagnostic testing facility (IDTF) may perform only procedures that are exempt from CLIA. An entity that owns both an IDTF and an independent laboratory should therefore enroll them as discrete Ohio medicaid providers.

(B) When an IDTF performs a procedure for a hospital patient, it will not receive medicaid payment directly but must instead make separate arrangements to receive payment from the hospital.

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5160-11-09 **Laboratory-related services: claim payment.**

(A) Any laboratory provider using the Ohio department of health (ODH) laboratory to perform a covered laboratory-related procedure for a medicaid-eligible individual must prepare specimens and complete necessary paperwork in accordance with all applicable ODH rules and practices. The laboratory provider is exempt from paying the ODH laboratory for the service; instead, the department will pay the ODH laboratory. The laboratory provider must not submit claims to the department for such procedures.

(B) For a covered global radiology procedure and its professional and technical components, the medicaid maximum payment amounts are specified in rule 5160-4-25 of the Administrative Code.

(C) For a covered laboratory-related service represented by a new healthcare common procedure coding system (HCPCS) procedure code that takes effect at the beginning of a calendar year, the initial maximum payment amount is established in accordance with rule 5160-1-60 of the Administrative Code.

(D) For any other covered laboratory-related service (global procedure, professional component, or technical component), the initial payment amount is the lesser of the submitted charge or the applicable medicaid maximum from the following list:

(1) For a service that is payable under the clinical laboratory fee schedule published by CMS, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service; or

(2) For a service that is payable under the medicare physician fee schedule, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service.

(3) For dates of service beginning January 1, 2018, the applicable payment amounts for clinical laboratory, molecular pathology, and pathology procedures are reduced by five percent.

(E) If the medicare amount for a service becomes less than the current medicaid maximum payment amount, then the medicaid maximum payment amount for that service is reestablished on the basis of the new medicare amount:

(1) For a service that is payable under the clinical laboratory fee schedule published by CMS, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service; or

(2) For a service that is payable under the medicare physician fee schedule, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service.

(3) For dates of service beginning January 1, 2018, the applicable payment amounts for clinical laboratory, molecular pathology, and pathology procedures are reduced by five per cent.

(F) Both the medicare physician fee schedule and the clinical laboratory fee schedule are available from CMS, http://www.cms.gov.

(G) For convenience, a list of medicaid maximum payment amounts and additional claim-related information for clinical diagnostic procedures, molecular pathology procedures, and physician pathology procedures is available on the department's 'Fee Schedule and Rates' web page, which may be accessed through the department's main web page (http://medicaid.ohio.gov).

(H) The payment provisions of this rule supersede entries in appendix DD to rule 5160-1-60 of the Administrative Code that pertain to laboratory-related services.

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5160-11-11 **Laboratory services.**

(A) Definitions and explanations that apply to this chapter of the Administrative Code.

(1) "Clinical consultation" is the formal evaluation by a physician or other qualified healthcare professional, performed on the written order of a treating practitioner, of test results that appear to be abnormal. Payment for the clinical consultation is based on the physician fee schedule relative value file published by the centers for medicare and medicaid services (CMS). (The procedure code used for clinical consultation is different and separate from the procedure code for the test whose results are being evaluated.)

(2) "Clinical pathology interpretation" is the interpretation, performed on the written order of a treating practitioner by another practitioner, of the results of any of a certain group of clinical diagnostic procedures that are distinguished by three shared traits:

(a) Separate payment may be made for interpretation;

(b) Payment for the clinical diagnostic procedures themselves is based on the clinical laboratory fee schedule published by CMS; and

(c) Payment for the clinical pathology interpretation is based on the physician fee schedule relative value file published by CMS. (The procedure code for the clinical pathology interpretation consists of a professional component modifier appended to the relevant clinical diagnostic procedure code.)

(3) "Eligible provider" has the same meaning as in rule 5160-1-17 of the Administrative Code.

(4) "Global procedure" or "total procedure" is a procedure, in its entirety, that comprises both a technical component (the part of a laboratory procedure that relies on the technical skill of a trained individual to secure a specimen and prepare it for analysis) and a professional component (the part of a laboratory procedure that relies on the professional skill or training of a physician or other qualified healthcare professional to analyze the results produced by the technical component and to provide a written report of findings).

(5) "Independent" means separate from an attending or consulting practitioner's office or group practice, an ambulatory surgery center, a hospital, or a nursing facility. A laboratory facility under the ownership and direction of an individual

practitioner or group practice is considered to be independent if it is represented to other practitioners that both the owners and directors and the facility itself are available for the performance of procedures.

(6) "Routine procedure" is a procedure for which no separate payment is made for either of two reasons:

(a) It is very common and is performed only in connection with another procedure (e.g., the collection of a clean-catch urine sample or a throat swab); or

(b) It is included in a treatment protocol for which a composite payment amount has been established (e.g., a specific laboratory test performed for an individual receiving dialysis, the reading by automated glucose monitor of blood samples taken from nursing facility residents who have diabetes).

(7) For purposes of medicaid, most covered laboratory procedures fall into two main categories.

(a) For the performance of clinical diagnostic procedures, no highly specialized skill is needed (such as the knowledge and training of a physician or other qualified healthcare professional).

(i) Clinical diagnostic procedures have no separate professional and technical components.

(ii) Performance of these procedures is generally predicated on certification of the laboratory provider under the "Clinical Laboratory Improvement Amendments of 1988" (CLIA, Pub. L. No. 100-578, 42 U.S.C. 263a as in effect on July 1, 2020).

(iii) Payment for these procedures is based on the clinical laboratory fee schedule published by CMS.

(b) The performance of professional procedures relies on the skill and training of a physician or other qualified healthcare professional, usually a pathologist or a hematologist.

(i) Pathology procedures have both a professional component and a technical component. In most instances, these components are distinguished on claims by the inclusion of a modifier along with the procedure code. (The professional and technical components of a few procedures may be represented by separate procedure codes.)

The professional component of a pathology procedure represents the professional services a practitioner renders in the performance of the procedure. It does not represent the simple reading of test results, which is included in the associated originating service (e.g., office visit or surgery).

(ii) Some procedures are exclusively professional in nature and have no technical component.

(iii) Only an eligible practitioner or an independent laboratory submitting claims on behalf of its eligible practitioners may receive payment for a professional procedure (or a professional component of a procedure).

(iv) Payment for pathology procedures and for other professional procedures or components of procedures is based on the physician fee schedule relative value file published by CMS. (There are a very few exclusively technical procedures for which payment is also based on the physician fee schedule relative value file.)

(B) Providers.

(1) Providers. An entity may enroll in medicaid as a laboratory provider only if the following conditions are satisfied:

(a) The entity holds appropriate certification under CLIA; and

(b) The laboratory procedures it performs are within its usual scope.

(2) A facility that only collects or prepares specimens or that functions only as a mailing service and does not perform testing is not considered to be a laboratory.

(C) Coverage.

(1) 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 services but rather as hospital services:

(a) A clinical diagnostic procedure performed for a hospital inpatient; and

(b) The technical component of a pathology procedure performed for a hospital inpatient.

(2) Payment can be made only for a laboratory service or procedure that, in accordance with Chapter 5160-1 of the Administrative Code, is medically necessary or is medically indicated when performed in conjunction with a covered preventive health service.

(3) A laboratory provider obtains and maintains appropriate documentation.

(a) Although a laboratory service may be rendered on the verbal order of a physician or other qualified healthcare professional, the laboratory provider may submit a claim only after it has obtained a written order. A written order may consist of an entry in a person's medical records (e.g., in an individual practitioner's office, a group practice, or a hospital). A written order includes the following information:

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

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

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

(iv) At least one appropriate diagnosis code;

(v) The date of the order;

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

(vii) 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, the individual's age or date of birth, an indication of previous abnormal results and subsequent actions).

(b) A written order may be given in any industry-recognized format, such as handwriting, typed text, or electronic transmission.

(c) No separate written order is needed for a medically necessary follow-up procedure (e.g., a quantitative test performed in response to a positive qualitative test result) so long as the procedure is performed in accordance with appropriate standard practices and is included in the laboratory provider's written protocols. A written order is needed for

any additional procedure that is based solely on a laboratory provider's internal protocols.

(d) A laboratory provider is to keep the following records for the period of time specified in rule 5160-1-17.2 of the Administrative Code:

(i) A copy of each written order for a procedure or service (clinical diagnostic procedure, pathology procedure, consultation, or interpretation);

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

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

(4) Payment may be made to a physician or other qualified healthcare professional (such as a pathologist or a hematologist) for the following professional laboratory services:

(a) The professional component of a pathology procedure;

(b) A global pathology procedure that was performed in the practitioner's own full-service, in-office laboratory (certified for the performance of the technical component) on a specimen obtained from an individual who was not a hospital patient;

(c) A clinical pathology consultative service; or

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

(5) Specific coverage provisions apply to certain groups of services and procedures.

(a) Referred procedures.

(i) 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 FQHC or RHC 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) At the request of the department, 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 routinely refers to the reference laboratory.

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

(b) Procedures bundled into a panel.

(i) Altered descriptions of a particular panel are not to be used in place of the official description established by a national authority such as the American medical association or the centers for medicare and medicaid services.

(ii) When a provider performs all of the constituent procedures of a covered panel (and all of the constituent procedures are medically necessary or medically indicated), the entire panel is reported on a claim rather than the separate constituent procedures.

(iii) When a provider performs some but not all of the constituent procedures of a panel, the separate constituent procedures are reported on a claim.

(iv) When a provider performs more procedures than are included in a panel, both the panel and the additional procedures are reported on a claim.

(c) Specimen collection.

(i) Specimen collection performed in a nursing facility, skilled nursing facility, or intermediate care facility for individuals with intellectual disabilities is not a laboratory service.

(ii) Payment as laboratory services may be made only for the following specimen 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.

(iii) 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 needed for a single test (e.g., a glucose tolerance test).

(iv) Only the eligible provider that performs a specimen collection may receive payment for it.

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

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

(vii) No payment is made for the following specimen 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.

(d) Evocation/suppression testing.

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

(ii) Separate payment may be made to a physician or other qualified healthcare professional 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.

(iii) 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).

(iv) Separate payment may be made to a physician or other qualified healthcare professional 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.

(e) Neonatal diagnostic screening. Payment for neonatal diagnostic screening may be made to a physician laboratory provider, a professional medical group laboratory provider, a hospital laboratory provider, or a clinic laboratory provider if both of the following conditions are satisfied:

(i) The procedure was performed with a prefabricated laboratory kit purchased from the Ohio department of health (ODH) laboratory and used for screening a newborn infant for genetic, endocrine, or metabolic disorders listed in Chapter 3701-55 of the Administrative Code; and

(ii) 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.

(f) Urine drug screening.

(i) The performance of drug screening by urinalysis is subject to the following frequency limits, which may be exceeded with prior authorization:

(a) For presumptive screens, thirty dates of service per benefit year; and

(b) For definitive tests, twelve dates of service per benefit year.

(ii) Prior authorization is needed for a definitive drug test involving twenty-two or more drug classes on a single date of service.

(6) Non-covered laboratory services.

(a) No payment is made for the following services:

(i) Laboratory services exceeding the provisions set forth in this chapter for which no prior authorization has been given;

(ii) Routine laboratory or screening procedures;

(iii) Laboratory services for which a laboratory provider is not appropriately certified under CLIA;

(iv) Laboratory services rendered in conjunction with those non-covered services that are delineated in rule 5160-1-61 of the Administrative Code; and

(v) Laboratory services rendered for forensic investigation, autopsy, or paternity testing.

(b) 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 service for which it lacks the necessary CLIA certification.

(D) Claim payment.

(1) When submitting a claim to the department, a laboratory provider is to use the code that describes the procedure in the most detail.

(a) 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 therefore needs to be taken in the selection of the most appropriate procedure code.

(b) 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. For such a service, the laboratory provider submits a claim "by report" in accordance with rule 5160-1-60.4 of the Administrative Code and notes the analyte, the specimen type, and the method 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.

(2) When a laboratory provider uses the Ohio department of health (ODH) laboratory to perform a covered laboratory procedure for a medicaid-eligible individual, the laboratory provider prepares specimens and completes necessary paperwork in accordance with all applicable ODH rules and practices. The laboratory provider is exempt from paying the ODH laboratory for the service; instead,

the department will pay the ODH laboratory. Claims for such procedures are not to be submitted to the department.

(3) For a covered laboratory service represented by a new healthcare common procedure coding system (HCPCS) procedure code, the initial maximum payment amount is established in accordance with rule 5160-1-60 of the Administrative Code.

(4) For any other covered laboratory service (global procedure, professional component, or technical component), the initial payment amount is the lesser of the submitted charge or the applicable medicaid maximum from the following list:

(a) For a service that is payable under the clinical laboratory fee schedule published by CMS, seventy-five per cent of the Ohio-specific medicare allowed amount for that service; or

(b) For a service that is payable under the medicare physician fee schedule, seventy-five per cent of the Ohio-specific medicare allowed amount for that service.

(5) If the medicare amount for a service becomes less than the current medicaid maximum payment amount, then the medicaid maximum payment amount for that service is reestablished on the basis of the new medicare amount:

(a) For a service that is payable under the clinical laboratory fee schedule published by CMS, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service; or

(b) For a service that is payable under the medicare physician fee schedule, it is seventy-five per cent of the Ohio-specific medicare allowed amount for that service.

(6) Both the medicare physician fee schedule and the clinical laboratory fee schedule are available from CMS, http://www.cms.gov.

(7) For convenience, a list of medicaid maximum payment amounts and additional claim-related information for clinical diagnostic procedures, molecular pathology procedures, and pathology procedures is available on the department's 'Fee Schedule and Rates' web page, which may be accessed through the department's main web page (http://medicaid.ohio.gov).

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5160-11-21 **Portable x-ray supplier services.**

(A) Providers. An entity may enroll in medicaid as a portable x-ray supplier only if it meets the following criteria:

(1) It complies with the conditions set forth in 42 C.F.R. part 486 subpart C (October 1, 2019); and

(2) It is enrolled in medicare as a supplier of portable x-ray services.

(B) Coverage.

(1) The radiology procedures performed by a portable x-ray supplier have both a professional component and a technical component.

(a) In general, a portable x-ray supplier performs the technical component of a procedure.

(b) A portable x-ray supplier may receive payment for the technical component alone if it performs only the technical component and the professional component is performed by a physician or other qualified healthcare professional not associated with the portable x-ray supplier by ownership, employment, or contract (e.g., interpretation of an x-ray is performed by an individual's treating practitioner).

(c) A portable x-ray supplier may receive payment for a global procedure if it performs both the professional and the technical components and the professional component is performed by a physician or other qualified healthcare professional who owns, is employed by, or is under contract with the portable x-ray supplier.

(d) A portable x-ray supplier cannot receive payment for the professional component alone.

(2) For payment purposes, only the following radiology procedures are considered to be portable x-ray services:

(a) Skeletal imaging involving the extremities, pelvis, vertebral column, and skull;

(b) Chest imaging;

(c) Abdominal imaging; and

(d) Diagnostic mammography if the provider meets the conditions set forth in 21 C.F.R. part 900 subpart B (April 1, 2019).

(3) Provisions affecting payment for radiology services are set forth in rule 5160-4-25 of the Administrative Code.

(4) No payment is made for the following procedures when they are performed by a portable x-ray supplier:

(a) Procedures involving fluoroscopy;

(b) Procedures involving the use of a contrast medium;

(c) Procedures involving the administration of a substance to the individual, the injection of a substance into the individual, or special manipulation of the individual;

(d) Procedures involving special medical skill or knowledge possessed by a physician or other qualified healthcare professional or the exercise of medical judgment;

(e) Procedures involving special technical competency or special equipment or materials not ordinarily needed for radiography;

(f) Routine screening procedures; and

(g) Procedures that are not of a diagnostic nature.

(5) Payment is available for the one-way transportation of portable x-ray equipment to a medicaid-eligible individual's place of residence. For each visit, only one equipment transportation charge is allowed, regardless of the number of persons served.

(C) Claim payment. For a covered global radiology procedure and its professional and technical components and for covered transportation of portable x-ray equipment, the medicaid maximum payment amounts are indicated in appendix DD to rule 5160-1-60 of the Administrative Code.

Replaces: 5160-11-03.2, part of 5160-11-01, part of 5160-11-02, part of 5160-11-09

Effective:

Five Year Review (FYR) Dates:

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Certification

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5160-11-31 **Independent diagnostic testing facility (IDTF) services.**

(A) Providers.

(1) An entity may enroll in medicaid as an independent diagnostic testing facility (IDTF) only if it meets the following criteria:

(a) It meets all standards set forth in and provide services in accordance with 42 C.F.R. 410.33 (October 1, 2019);

(b) It is enrolled in medicare as an IDTF;

(c) It takes the following measures to establish accountability:

(i) It ensures that each supervising practitioner attests 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 practitioner owns the facility, in whole or in part, and employs the operating personnel; or

(b) The practitioner 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 conditions for federal, state, and local licensure and registration; and ensuring that safe operating procedures and quality control procedures are used;

(ii) It maintains and updates procedure and quality control manuals; and

(iii) It keeps all records of quality control must be kept for the period of time specified in rule 5160-1-17.2 of the Administrative Code; and

(d) It performs only procedures that are not subject to the "Clinical Laboratory Improvement Amendments of 1988" (CLIA, Pub. L. No. 100-578, 42 U.S.C. 263a as in effect on July 1, 2020).

(2) An entity that owns both an IDTF and an independent laboratory should enroll them as discrete Ohio medicaid providers.

(3) An entity may enroll in medicaid as a mammography supplier (a facility or an entity established solely for the provision of mammography services) only if it meets the following criteria:

(a) It participates in medicaid as an IDTF; and

(b) It complies with the conditions set forth in 42 C.F.R. 410.34 (October 1, 2019).

(B) Coverage. Provisions affecting payment for radiology services are set forth in rule 5160-4-25 of the Administrative Code.

(C) Claim payment.

(1) No separate payment is made to an IDTF that performs a procedure in a hospital setting. Instead, the provider makes payment arrangements directly with the participating hospital.

(2) For a covered global radiology procedure and its professional and technical components, the medicaid maximum payment amounts are indicated in appendix DD to rule 5160-1-60 of the Administrative Code.

Replaces: 5160-11-03.3, part of 5160-11-01, part of 5160-11-02, part of 5160-11-09

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