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5101:3-11-02 **Independent laboratory, portable x-ray supplier, and independent diagnostic testing facility: eligible providers.**

(A) Independent laboratory.

(1) All independent laboratories that are allowed to provide services under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 are eligible to participate in the medicaid program and provide covered laboratory services upon execution of the standard Ohio medicaid provider agreement.

(2) Laboratory services may also be provided and billed by any medicaid provider who is certified to perform laboratory procedures under CLIA. This would include, but is not limited to, the following eligible medicaid providers:

(a) Outpatient hospital laboratories;

(b) Physicians and physician group practices;

(c) Podiatrists and podiatric group practices;

(d) Ambulatory health care centers (clinics);

(e) Rural health clinics (RHCs);

(f) Outpatient health facilities (OHFs);

(g) Federally qualified health centers (FQHCs); and

(h) Ambulatory surgery centers (ASCs).

(3) All providers of laboratory services must comply with the requirements set forth in the "Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)". Only providers which meet the following criteria will be eligible for reimbursement for laboratory services provided on or after September 1, 1992:

(a) The provider must possess a current, unrevoked and unsuspended

certificate of waiver, physician-performed microscopy procedure (PPMP) certificate, registration certificate, certificate, or certificate of accreditation; or

(b) The provider must be certified by the national institute on drug abuse (NIDA) for drug screening services; or

(c) The provider must be an independent laboratory or operate a laboratory that is a component of or functions under the veteran's administration (VA) or the department of defense (DOD).

(4) The type of certification required for participation is dependent on the type of tests the laboratory performs: waivered tests, PPMP tests, moderate complexity (formerly level I) tests or high complexity (formerly level II) tests. ~~Rule 5101:3-11-09 of the Administrative Code contains~~Current CLIA regulations contain the lists of covered procedures that are categorized as waivered tests or PPMP tests and the HCPCS codes that must be billed by providers only possessing a certificate of waiver or a PPMP certificate. Rule 5101:3-11-10 of the Administrative Code provides a list of radiology tests that are subject to the CLIA regulations.

(a) Providers who possess only a certificate of waiver will be restricted to performing and billing for the procedures listed in the current CLIA regulations.~~paragraph (A) of rule 5101:3-11-09 of the Administrative Code.~~

(b) Providers who possess only a PPMP certificate will be restricted to performing and billing for the procedures listed in the current CLIA regulations.~~paragraphs (A) and (B) of rule 5101:3-11-09 of the Administrative Code.~~

(c) Providers who possess a certificate of registration, a certificate, or a certificate of accreditation may bill for:

(i) All waivered tests;

(ii) All PPMP tests;

(iii) Moderate complexity tests, if the provider meets the requirements set forth in section 493.20 of the Code of Federal Regulations (CFR); and

(iv) High complexity tests, if the provider meets the applicable requirements in section 493.25 of the Code of Federal Regulations (CFR).

(B) Portable x-ray supplier.

All suppliers of portable x-ray services who are in compliance with 42 CFR 486 part C and are certified under the medicare program are eligible to participate in the medicaid program upon the completion of the standard Ohio medicaid provider agreement.

(C) Independent diagnostic testing facility.

(1) The following entities are eligible to participate in the medicaid program as an independent diagnostic testing facility and provide covered diagnostic testing facility services and/or mammography services upon the execution of the standard Ohio medicaid provider agreement if the entity is in compliance with the conditions set forth in paragraphs (C)(2)(a) to (C)(2)(c) of this rule, in regard to the type of services performed, and either:

(a) Meets the definition of independent diagnostic testing facility defined in rule 5101:3-11-01 of the Administrative Code and possesses a current unrevoked or unsuspended medicare provider number as an independent diagnostic testing facility; or

(b) Meets the definition of independent mammography supplier defined in rule 5101:3-11-01 of the Administrative Code and possesses a current unrevoked or unsuspended medicare provider number as a mammography supplier.

(2) Conditions of coverage of independent diagnostic testing facility services.

(a) The independent diagnostic testing facility must be in conformity with all applicable federal, state, and local laws and regulations.

(b) An independent diagnostic testing facility must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the facility including the qualification of the nonphysician personnel, the operation and calibration of the equipment, and the quality of the testing performed. The supervising physician must personally furnish supervision whether the procedure is performed at a fixed location or a mobile facility.

(c) Diagnostic testing services may be covered if the following conditions are met:

(i) The services are performed under the general supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the specific diagnostic tests as defined below:

(a) The physician has attained board certification in the appropriate specialty(s); or

(b) The physician who is not board certified must document completion of a training program approved by a recognized accrediting body and evidence proficiency in the test(s) being supervised as required by the appropriate specialty and described in medicare regulations.

(ii) All nonphysician personnel used by the independent diagnostic testing facility must demonstrate the basic qualifications to perform the tests and have training and proficiency as evidenced by licensure or certification by the appropriate state department. If no state board exists for the testing in question, then certification by an appropriate national credentialing body is acceptable

(iii) Radiology procedures are conducted in compliance with radiology safety standards which assure that the equipment and the operating procedures used minimize the radiation exposure and hazards for patients, personnel, and other persons in the immediate environment.

(iv) Radiology or mammography equipment and shielding are inspected by qualified individuals at intervals not greater than every twenty-four months.

(d) The supervising physician(s) must certify in writing upon application, initially and every two years thereafter, that:

(i) He/she owns or partially owns the facility and employs the operating personnel; or

(ii) He/she is at least a part-time employee or an employee under

contract whose responsibilities include checking the procedural and quality control manuals, observing the operator's or technician's performance, verifying that the equipment and personnel meet applicable federal, state, and local licensure and registration requirements, and assuring safe operating procedures and quality control procedures are used.

(e) Updated procedural and quality control manuals must be maintained by the facility. All records of quality control must be maintained for a period of six years.

Effective:

R.C. 119.032 review dates: 10/7/2002

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Certification

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Date

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