

CHAPTER 1243. OUTPATIENT LABORATORY SERVICES

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Authority

The provisions of this Chapter 1243 issued under sections 403, 443.3(1) and 443.3(2)(i) of the Public Welfare Code (62 P. S. §§ 403, 443.3(1) and 443.3(2)(i)), unless otherwise noted.

Source

The provisions of this Chapter 1243 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614, unless otherwise noted.

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Cross References

This chapter cited in 55 Pa. Code § 1101.31 (relating to scope); and 55 Pa. Code § 1101.95 (relating to conflicts between general and specific provisions).

§ 1243.1. Policy.

The MA Program provides payment for specific outpatient laboratory services rendered to eligible recipients by laboratories enrolled as providers under the Program. Payment for outpatient laboratory services is subject to this chapter and Chapters 1101 and 1150 (relating to general provisions; and MA Program payment policies) and the MA Program fee schedule.

Authority

The provisions of this section are amended under sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Source

The provisions of this § 1243.1 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932; amended September 30, 1988, effective October 1, 1988, 18 Pa.B. 4418; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4898. Immediately preceding text appears at serial page (313036).

§ 1243.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

CLIA—The Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C.A. § 263a).

Laboratory—A facility for the biological, microbiological, serological, chemical, immunohe-matological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens, or both, or only serving as a mailing service and not performing testing are not considered laboratories.

Panel test—A series of diagnostically related laboratory tests ordered by a practitioner to confirm a presumptive diagnosis.

Authority

The provisions of this section are amended under sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Source

The provisions of this § 1243.2 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4898. Immediately preceding text appears at serial page (313036).

SCOPE OF BENEFITS

§ 1243.21. Scope of benefits for the categorically needy.

Categorically needy recipients are eligible for the outpatient laboratory services listed in the MA Program fee schedule.

Source

The provisions of this § 1243.21 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932; amended September 30, 1988, effective October 1, 1988, 18 Pa.B. 4418. Immediately preceding text appears at serial page (117512).

§ 1243.22. Scope of benefits for the medically needy.

Medically needy recipients are eligible for the outpatient laboratory services listed in the MA Program fee schedule.

Source

The provisions of this § 1243.22 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932; amended September 30, 1988, effective October 1, 1988, 18 Pa.B. 4418. Immediately preceding text appears at serial page (117513).

§ 1243.23. Scope of benefits for State Blind Pension recipients.

State Blind Pension recipients are not eligible for outpatient laboratory services unless they are also either categorically or medically needy.

Source

The provisions of this § 1243.23 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614.

§ 1243.24. Scope of benefits for General Assistance recipients.

General Assistance recipients, age 21 to 65, whose MA benefits are funded solely by State funds, are eligible for medically necessary basic health care benefits as defined in Chapter 1101 (relating to general provisions). See § 1101.31(e) (relating to scope).

Source

The provisions of this § 1243.24 adopted December 11, 1992, effective January 1, 1993, 22 Pa.B. 5995.

PROVIDER PARTICIPATION**§ 1243.41. Participation requirements.**

In addition to the participation requirements established in Chapter 1101 (relating to general provisions) laboratories shall meet the following requirements:

- (1) Each laboratory, whether in or out-of-State, shall submit the following to the Department:
 - (i) A copy of its CLIA certificate.
 - (ii) A copy of its CLIA identification number.
 - (iii) A list of diagnostic procedures that the laboratory is CLIA-certified to perform with the corresponding Healthcare Common Procedure Coding System (HCPCS) codes.
 - (iv) The fee currently charged to the general public for each of the procedures.
- (2) For hospital laboratories, the hospital shall be currently Medicare certified or currently certified by the Department of Health as meeting standards comparable to those of Medicare.
- (3) A laboratory shall be currently licensed by the Department of Health, Bureau of Laboratories and be Medicare certified under Title XVIII (42 U.S.C.A. §§ 1395—1395hhh), or certified as meeting standards comparable to those of Medicare.
- (4) Out-of-State laboratories shall meet the applicable requirements established in paragraphs (1) and (2) and shall sign the provider agreement designated by the Department.

Authority

The provisions of this section are amended under sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Source

The provisions of this § 1243.41 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4898. Immediately preceding text appears at serial pages (276177) to (276178).

Cross References

This section cited in 55 Pa. Code § 1243.52 (relating to payment conditions for various services).

§ 1243.42. Ongoing responsibilities of providers.

In addition to the ongoing responsibilities established in § 1101.51(a)—(e) (relating to ongoing responsibilities of providers), laboratories shall, as a condition of participation, comply with the following requirements:

- (1) Promptly report to the Department changes in the laboratory's CLIA certification, including changes in the type of CLIA certificate, changes in laboratory fees or procedures and the effective date of these changes.

(2) Permit authorized State and Federal officials or their authorized agents to conduct onsite reviews for the purpose of verification of information furnished as a basis for payment under the MA Program. During the course of the review, the reviewers shall be allowed access to the laboratory area. The provider shall also allow reviewers access to laboratory procedure manuals and any records or documents necessary to determine whether payment for services that have or are being provided comply with Federal and State laws and regulations. The reviewers shall be allowed to photograph, photocopy or duplicate the manuals, records, and documents. Onsite reviews shall be conducted during the normal hours of operation or at another time mutually agreeable to the officials and the provider.

(3) Laboratories shall avoid locked-in referral arrangements between themselves and a prescriber.

Authority

The provisions of this section are amended under sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Source

The provisions of this § 1243.42 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4898. Immediately preceding text appears at serial page (276178).

Cross References

This section cited in 55 Pa. Code § 1243.71 (relating to scope of claims review procedures).

PAYMENT FOR OUTPATIENT LABORATORY SERVICES

§ 1243.51. General payment policy.

Payment is made for covered services provided by participating laboratories subject to the conditions and limitations established in this section and § 1243.53 (relating to limitations on payment) and Chapters 1101 and 1150 (relating to general provisions; and MA Program payment policies) and the MA Program fee schedule.

Source

The provisions of this § 1243.51 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932; amended September 30, 1988, effective October 1, 1988, 18 Pa.B. 4418. Immediately preceding text appears at serial pages (117514) to (117515).

§ 1243.52. Payment conditions for various services.

(a) If a laboratory refers work to another laboratory, payment will be made to either the referring laboratory or the laboratory actually performing the test. Payment will be made only if the laboratory billing the Department is currently par-

participating in the MA Program and has listed the diagnostic procedure being billed with the Department as specified in § 1243.41(1) (relating to participation requirements).

(b) Laboratory procedures billed to the Department will be based on a written request of the practitioner. The written request must include the following:

- (1) The name of the practitioner, the Medical Assistance Identification (M.A.I.D.) number of the practitioner or the DEA number of the practitioner.
- (2) The name of the recipient.
- (3) The case number of the recipient.
- (4) The date of the request.
- (5) The handwritten signature of the practitioner or the designee of the practitioner.

(c) Preadmission laboratory tests performed by a hospital laboratory shall be included in the inpatient billing of the hospital. If the recipient is not admitted for some reason, the preadmission laboratory tests shall be billed as an outpatient claim.

Authority

The provisions of this section are amended under sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Source

The provisions of this § 1243.52 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4898. Immediately preceding page appears at serial page (276179).

Cross References

This section cited in 55 Pa. Code § 1243.52a (relating to clarification of the terms “written” and “signature”—statement of policy).

§ 1243.52a. Clarification of the terms “written” and “signature”—statement of policy.

(a) The term “written” in § 1243.52(b) (relating to payment conditions for various services) includes requests for laboratory procedures that are handwritten or transmitted by electronic means.

(b) Written requests transmitted by electronic means must be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation or use by any unauthorized person.

(c) The term “signature” in § 1243.52(b)(5) includes a handwritten or electronic signature that is made in accordance with the Electronic Transaction Act (73 P. S. §§ 2260.101—2260.5101).

Source

The provisions of this section § 1243.52a adopted July 16, 2010, effective July 17, 2010, 40 Pa.B. 3963.

§ 1243.53. Limitations on payment.

(a) The fees listed in the MA Program fee schedule are the maximum fees allowed under the MA Program.

(b) Section 1903(i)(1) of Title XIX of the Social Security Act (42 U.S.C.A. § 1396(i)(1)) provides that charges allowed for medical services, supplies, and equipment under Medicare Part B and Medicaid that, in the judgment of the Secretary of Health and Human Services (HHS) do not generally vary significantly from one provider to another, may not exceed the lowest charge levels at which the items and services are widely and consistently available in a locality. Certain laboratory procedures are presently subject to lowest charge levels. Other procedures shall be added to the list by HHS from time to time. For those selected procedures established by both Medicare and Medicaid, the lowest charge level adopted by the Medicare carrier shall control. For those selected procedures furnished only under Medicaid, the Department will set lowest charge levels according to the procedures used by Medicare. Medical Assistance maximum fees for laboratory procedures shall be periodically adjusted and published in the *Pennsylvania Bulletin* under the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1102, 1201—1208 and 1602); and 45 Pa.C.S. Chapters 5, 7 and 9, known as the Commonwealth Documents Law.

Source

The provisions of this § 1243.53 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932; amended September 30, 1988, effective October 1, 1988, 18 Pa.B. 4418. Immediately preceding text appears at serial pages (117515) to (117516).

Cross References

This section cited in 55 Pa. Code § 1243.51 (relating to general payment policy).

§ 1243.54. Noncompensable services.

Payment will not be made to a laboratory for the following services regardless of where or to whom they are provided:

- (1) Procedures not listed in the fee schedule in the MA Program fees schedule.
- (2) Travel to a recipient's place of residence to collect a specimen. The provider will be reimbursed for performing the procedure if it is compensable; however, no extra payment will be made for mileage.
- (3) Procedures that the laboratory is not CLIA-certified to perform.

Authority

The provisions of this section are amended under sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Source

The provisions of this § 1243.54 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614; amended December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932; amended September 30, 1988, effective October 1, 1988, 18 Pa.B. 4418; amended September 5, 2008, effective September 6, 2008, 38 Pa.B. 4898. Immediately preceding text appears at serial page (276180).

UTILIZATION REVIEW**§ 1243.71. Scope of claims review procedures.**

In addition to the utilization review procedures established in Chapter 1101 (relating to general provisions), the procedure manual of the laboratory shall be available to the representatives of the Department as specified in § 1243.42(2) (relating to ongoing responsibilities of providers).

Source

The provisions of this § 1243.71 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614.

ADMINISTRATIVE SANCTIONS**§ 1243.81. Provider misutilization.**

Providers determined to have billed for services inconsistent with MA Program regulations, to have provided services outside the scope of customary standards of laboratory practice, or to have otherwise violated the standard set forth in the provider agreement, are subject to the sanctions imposed in Chapter 1101 (relating to general provisions).

Source

The provisions of this § 1243.81 adopted December 5, 1980, effective December 1, 1980, 10 Pa.B. 4614.

APPENDIX A. [Reserved]**Source**

The provisions of this Appendix A reserved December 23, 1983, effective January 1, 1983, 13 Pa.B. 3932. Immediately preceding text appears at serial pages (58175) to (58177).

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