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Authority

The provisions of this Chapter 1121 issued under sections 403, 443.4, 443.6 and 444.1 of the Public Welfare Code (62 P. S. §§ 403, 443.4, 443.6 and 444.1), unless otherwise noted.

Source

The provisions of this Chapter 1121 adopted May 9, 1980, effective May 10, 1980, 10 Pa.B. 1879; amended June 29, 1984, effective July 1, 1984, 14 Pa.B. 2257, unless otherwise noted. Immediately preceding text appears at serial pages (69587) to (69588), (62904) to (62911), (75063) to (75066) and (51215) to (51218).

Notes of Decisions

Emergency regulations, which decreased Medicaid reimbursements to pharmacists who supply medications, were adopted in violation of a Federal act's prohibition against compliant states from reducing payments for covered outpatient drugs. *Pennsylvania Pharmaceutical Association v. Casey*, 800 F.Supp. 173, 175 (M. D. Pa. 1992).

Cross References

This chapter cited in 49 Pa. Code § 27.505 (relating to repositories); 55 Pa. Code § 1101.31 (relating to scope); 55 Pa. Code § 1101.95 (relating to conflicts between general and specific provisions); 55 Pa. Code § 1181.57 (relating to limitations on payment for prescription drugs); 55 Pa. Code § 1187.105 (relating to limitations on payment for prescription drugs); 55 Pa. Code § 1241.54 (relating to noncompensable services and items); and 55 Pa. Code § 6210.72 (relating to limitations on payment for prescription drugs).

GENERAL PROVISIONS**§ 1121.1. Policy.**

The MA Program provides payment for medically necessary pharmaceutical services furnished directly to eligible recipients by pharmacies enrolled as providers in the program. Payment for these services are subject to this chapter and Chapter 1101 (relating to general provisions).

§ 1121.2. Definitions.

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

AWP—The average wholesale price for a drug as found in the Department's pricing service publication.

Brand name—A registered trade name commonly used to identify a drug.

CMS—The Centers for Medicare and Medicaid Services.

CMS multisource drug—A multisource drug identified by CMS for which FFP is limited under 42 CFR 447.331—447.333 (relating to drugs: aggregate

upper limits of payment; upper limits for multiple source drugs; state plan requirements, findings and assurances).

Compounded prescription—A prescription that is prepared in the pharmacy by combining two or more ingredients and involves the weighing of at least one solid ingredient which shall be a compensable item or a legend drug in a therapeutic amount.

DESI drug—A drug product for which Federal Financial Participation FFP is not available under 42 CFR 441.25 (relating to less than effective drugs).

EAC—Estimated Acquisition Cost—As defined in 42 CFR 447.301 (relating to definitions).

Experimental drug—A drug or product currently being investigated under licensure by the FDA to determine its safety and effectiveness.

FDA—Food and Drug Administration.

FFP—Federal financial participation.

Federal upper limit—The per unit amount set for a multisource drug which is established by CMS under 42 CFR 447.332.

Generic drug—A drug that is “A-rated” by the FDA as therapeutically equivalent to the counterpart brand name drug.

Legend drug—A drug or product that under Federal law or State law can be dispensed only upon the order of a physician.

Licensed prescriber—A person currently licensed under the law of a state to order medication.

Multisource drug—A drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

Nonlegend drug—A drug or product that can be purchased without a prescription.

OBRA '90—The Omnibus Budget Reconciliation Act of 1990 (Pub. L. No. 101-508, 104 Stat. 1388).

Pricing service—A third-party source that compiles and provides drug-specific information needed to maintain the drug reference file under this chapter.

State MAC—The maximum allowable cost established for a multisource drug.

Usual and customary charge—The pharmacy’s lowest net charge an MA recipient would pay for a prescription as a non-Medicaid patient at the time of dispensing for the same quantity and strength of a particular drug or product, including applicable discounts, such as special rates to nursing home residents, senior citizens, or other discounts extended to a particular group of patients, including generic drug discount and savings programs. This lowest net price does not apply to special in-store rates or discounts extended to charitable

organizations, religious groups, store employees and their families, nonprofit organizations, members of the medical profession or other similar non-Medicaid groups.

WAC—Wholesale Acquisition Cost—The manufacturer's list price for a drug to wholesalers or direct purchasers in the United States as listed in one or more available Nationally recognized pricing services.

Authority

The provisions of this § 1121.2 amended under sections 201(2), 403(b), 403.1, 443.4 and 454 of the Public Welfare Code (62 P. S. §§ 201(2), 403(b), 403.1, 443.4 and 454).

Source

The provisions of this § 1121.2 amended December 14, 1990, effective January 11, 1991, 20 Pa.B. 6167; amended January 24, 1992, effective upon publication and apply retroactively to April 1, 1991 for the Manufacturers' Rebate Program and September 1, 1991 for the pharmacy dispensing fee increase, 22 Pa.B. 361; amended September 22, 1995, effective September 23, 1995, 25 Pa.B. 3978; amended August 5, 2005, effective August 10, 2005, Pa.B. 4309; amended August 19, 2005, effective August 22, 2005, 35 Pa.B. 4727; corrected August 26, 2005, effective August 22, 2005, 35 Pa.B. 4823; amended April 13, 2012, effective April 14, 2012, 42 Pa.B. 2015. Immediately preceding text appears at serial pages (351422) and (312941) to (312942).

(Editor's Note: This regulation was promulgated under section 6(b) of the Regulatory Review Act (71 P. S. § 745.6(b)).)

COVERED AND NONCOVERED SERVICES

§ 1121.11. Types of services covered.

(a) The MA Program covers legend drugs except as otherwise specified in this chapter if the medical necessity has been established and the drug has been prescribed or ordered by a licensed prescriber within the scope of the prescriber's practice.

(b) The MA Program covers the nonlegend drugs specified in § 1121.53(d) (relating to limitations on payment), except that for GA recipients, coverage of nonlegend drugs is limited to insulin and drugs that the Department has identified as the preferred drug in a therapeutic class.

(c) Payment is subject to the conditions and limitations of this chapter and Chapter 1101 (relating to general provisions).

Authority

The provisions of this § 1121.11 amended under sections 201(2), 403(b), 443.4 and 454 of the Public Welfare Code (62 P. S. §§ 201(2), 403(b), 443.4 and 454).

Source

The provisions of this § 1121.11 amended August 5, 2005, effective August 10, 2005, 35 Pa.B. 4309. Immediately preceding text appears at serial page (251190).

Cross References

This section cited in 55 Pa. Code § 1124.24 (relating to scope of benefits for GA recipients).

§ 1121.12. Outpatient services.

Outpatient pharmaceutical services are only covered when provided in accordance with this chapter and Chapter 1101 (relating to general provisions).

§ 1121.13. [Reserved].**§ 1121.14. Noncovered services.**

Payment will not be made to a pharmacy for pharmaceutical services provided to a hospitalized recipient.

SCOPE OF BENEFITS**§ 1121.21. Scope of benefits for the categorically needy.**

Categorically needy recipients are eligible for medically necessary pharmaceutical services covered by the MA Program, subject to the conditions and limitations of this chapter.

§ 1121.22. Scope of benefits for the medically needy.

Medically needy recipients are not eligible for pharmaceutical services covered by the MA Program unless one of the following occurs:

- (1) If a compensable item or service is prescribed through the School Medical Program as described in § 1101.32(a)(2) (relating to coverage variations).
- (2) If a compensable item or service is prescribed for the purpose of family planning.
- (3) If a compensable vaccine is prescribed through the Early and Periodic Screening, Diagnosis and Treatment Program as described in § 1101.32(a)(1).

§ 1121.23. Scope of benefits for State Blind Pension recipients.

State Blind Pension recipients are eligible for medically necessary pharmaceutical services covered by the MA Program, subject to the conditions and limitations of this chapter.

§ 1121.24. Scope of benefits for GA recipients.

GA recipients, age 21 to 65, are eligible for medically necessary basic health care benefits as described in Chapter 1101 (relating to general provisions) and this chapter. See §§ 1101.31(e) and 1121.11 (relating to scope; and types of services covered).

Authority

The provisions of this § 1121.24 amended under sections 201(2), 403(b), 443.4 and 454 of the Public Welfare Code (62 P. S. §§ 201(2), 403(b), 443.4 and 454).

Source

The provisions of this § 1121.24 amended August 5, 2005, effective August 10, 2005, 35 Pa.B. 4309. Immediately preceding text appears at serial page (251191).

PROVIDER PARTICIPATION**§ 1121.41. Participation requirements.**

Participation requirements are established in §§ 1101.41—1101.43 and 1101.51. Each participating pharmacy must be separately enrolled and enter a separate provider agreement.

§ 1121.42. Ongoing responsibilities of providers.

In addition to the ongoing responsibilities established in Chapter 1101 (relating to general provisions) pharmacies shall, as a condition of participation, comply with the following requirements:

(1) 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 and for establishing the pharmacy's usual and customary charge to the general public as defined in Chapter 1101. During the course of the review, the reviewers shall be allowed access to the dispensing area. The provider shall allow reviewers access to records and documents necessary to determine whether payment for services is or was due under the Program and whether services that have been and are being provided comply with Federal and State law. The reviewer shall be allowed to photocopy, or duplicate these records and documents. These records include:

- (i) MA prescriptions on file.
- (ii) Non-MA prescriptions without the reviewer having access to patient identification.
- (iii) Pharmaceutical purchase invoices.
- (iv) The pricing system used by the store, including but not limited to, pricing rolodex, patient profile and pricing codes.
- (v) Price lists attached to prescription containers.

(2) Conform to accepted standards of practice and quality of service when dispensing prescriptions to MA recipients. It shall be considered contrary to accepted standards of practice for a pharmacy to differentiate between MA recipients and the general public, as defined in Chapter 1101.

Cross References

This section cited in 55 Pa. Code § 1121.71 (relating to scope of claims review procedures).

PAYMENT FOR PHARMACEUTICAL SERVICES**§ 1121.51. General payment policy.**

Payment is made for covered pharmaceutical services provided by participating pharmacies subject to the conditions and limitations in this section and §§ 1121.52—1121.56 and Chapter 1101 (relating to general provisions). Payment will not be made for a compensable pharmaceutical service if payment is available from another public agency or another insurance or health program. This does not apply to MA recipients whose drugs have been prescribed through the County Mental Health/Mental Retardation Programs operated under the Mental Health and Mental Retardation Act of 1966 (50 P. S. §§ 4101—4704). In this instance only, providers may bill the MA Program for services as specified in this chapter.

Cross References

This section cited in 55 Pa. Code § 1121.54 (relating to noncompensable services and items).

§ 1121.52. Payment conditions for various services.

(a) MA prescriptions, including those for recipients in skilled nursing facilities, intermediate care facilities or intermediate care facilities for the mentally retarded, which have been either written or verbally ordered by a licensed prescriber shall contain on the prescription form:

- (1) The name and address of the patient.
- (2) The name of the licensed prescriber.
- (3) The name, strength and quantity of the medication.
- (4) The directions for use.
- (5) The number of refills, if any.
- (6) The indication for “brand medically necessary”, when applicable, as specified in § 1121.53(b) (relating to limitations on payment).
- (7) The DEA number of the licensed prescriber, when controlled substances have been prescribed.
- (8) The professional license number of the licensed prescriber.

(b) The following service requires prior authorization as specified in § 1101.67 (relating to prior authorization): Each original prescription for single entity and multiple vitamins when prescribed for prenatal use. The Department will automatically issue a prior authorization for prescriptions indicating a diagnosis of pregnancy for single entity and multiple vitamins.

(c) For payment to be made for filling altered prescriptions, the pharmacy shall certify in writing on the prescription that the change was made by the licensed prescriber. Changes in the nature or brand of a medication, the strength of a medication, directions or quantity dispensed are acceptable only if the consent of the prescriber was obtained before dispensing. The written explanation of the pharmacy on the prescription must state that this was done and give the reasons for the change.

Cross References

This section cited in 55 Pa. Code § 1121.51 (relating to general payment policy); 55 Pa. Code § 1121.52a (relating to clarification of the term “written”—statement of policy); and 55 Pa. Code § 1121.54 (relating to noncompensable services and items).

§ 1121.52a. Clarification of the term “written”—statement of policy.

(a) The term “written” in § 1121.52(a) (relating to payment conditions for various services) includes prescriptions that are handwritten or transmitted by electronic means.

(b) Written prescriptions 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.

Source

The provisions of this § 1121.52a adopted July 16, 2010, effective July 17, 2010, 40 Pa.B. 3963.

§ 1121.53. Limitations on payment.

(a) The Department will not pay a provider an amount that exceeds the provider’s usual and customary charge to the general public.

(b) The Department establishes a State MAC which sets a limit on the drug cost component of the payment formula for selected multisource drugs. The State MAC will include a combination of CMS multisource drugs and the Department’s MAC drugs and does not apply if the following exist:

(1) The licensed prescriber certifies that a specific brand is medically necessary by doing all of the following:

(i) Writes on the prescription form “Brand Necessary” or “Brand Medically Necessary” in the prescriber’s own handwriting.

(ii) Receives prior authorization from the Department to use the brand name product.

(2) In the case of a telephone prescription, the licensed prescriber sends a properly completed prescription, as described in paragraph (1), to the pharmacist within 15 days of the date of service.

(c) Payment for prescriptions is limited to quantities consistent with the medical needs of the patient not to exceed a 34-day supply or 100 units, whichever is greater. Prescriptions may be refilled as long as the total authorization does not exceed a 6 months’ or five refill supply, whichever comes first, from the time of original filling of the prescription. Refills shall be authorized by the prescriber at the time the prescription is ordered, and the quantity dispensed on the refills may exceed the quantity prescribed on the initial prescription only if noted at the time the licensed prescriber orders the initial prescription.

(d) Payment for prescribed nonlegend drugs shall be limited to drugs and dosage forms listed in the following categories:

(1) Analgesics except long acting products.

(i) Acetaminophen and acetaminophen combinations in the form of tablets, capsules, suppositories, liquids and drops.

(ii) Aspirin and aspirin combinations in the form of tablets, capsules and suppositories.

(iii) Salicylates in the form of tablets, capsules and liquids.

(iv) Ibuprofen in its available dosage forms.

(2) Antacids.

- (3) Antidiarrheals.
 - (i) Kaolin-pectin combinations.
 - (ii) Loperamide in its available dosage forms.
- (4) Antiflatulents.
 - (i) Simethicone.
 - (ii) Simethicone combined with antacid.
- (5) Antinauseants.
 - (i) Concentrated balanced solutions of sugar and orthophosphoric acid.
 - (ii) Cyclizine lactate.
 - (iii) Dimenhydrinate.
 - (iv) Meclizine hydrochloride.
- (6) Bronchodilators.
- (7) Cough—cold preparations, not including mouthwashes, lozenges, troches, throat sprays or rubs, only when prescribed for MA recipients under 21 years of age.
- (8) Contraceptives.
- (9) Hematinics, not including long acting products.
 - (i) Ferrous fumarate.
 - (ii) Ferrous gluconate.
 - (iii) Ferrous sulfate.
- (10) Insulin and disposable insulin syringes.
- (11) Laxatives and stool softeners.
- (12) Nasal preparations.
 - (i) Oxymetazoline.
 - (ii) Phenylephrine.
 - (iii) Xylometazoline.
 - (iv) Naphazoline.
- (13) Ophthalmic preparations.
 - (i) Ocular lubricants containing polyvinyl alcohol or cellulose derivatives.
 - (ii) Phenylephrine in all ophthalmic forms.
 - (iii) Sodium chloride in strengths of 2% or greater in ophthalmic forms.
- (14) Topical products containing one or more of the following active ingredients.
 - (i) Anesthetics.
 - (A) Benzocaine.
 - (B) Cyclomethycaine.
 - (C) Dibucaine.
 - (D) Lidocaine.
 - (E) Pramoxine.
 - (F) Tetracaine.
 - (ii) Antibacterials.
 - (A) Bacitracin.

- (B) Neomycin.
- (C) Polymyxin.
- (D) Povidone-iodine.
- (E) Tetracycline.
- (iii) Dermatological baths.
 - (A) Colloidal oatmeal and combinations.
 - (B) Soya protein complex and combinations.
- (iv) Fungicidals.
 - (A) Iodochlorhydroxyquin (clioquinol).
 - (B) Miconazole nitrate.
 - (C) Salicylanilide.
 - (D) Salicylic acid.
 - (E) Sodium caprylate.
 - (F) Sodium propionate.
 - (G) Triacetin (glyceryl triacetate).
 - (H) Tolnaftate.
 - (I) Undecylenic acid, esters and salts.
- (v) Rectal preparations.
 - (A) Bismuth subgallate.
 - (B) Yeast.
 - (C) Zinc oxide.
- (vi) Tar preparations, not including soaps and cleansing agents.
- (vii) Wet dressings.
 - (A) Aluminum acetate.
 - (B) Aluminum sulfate.
 - (C) Calcium sulfate.
 - (D) Zinc sulfate.
- (15) Vitamins and minerals.
 - (i) Single entity and multiple vitamins with or without fluoride for children under 3 years of age.
 - (ii) Single entity and multiple vitamins when prescribed for prenatal use.
 - (iii) Nicotinic acid and its amides.
 - (iv) Calcium salts.
- (16) Diagnostic agents.
- (17) Quinine.
- (e) Payment for single entity and multiple vitamins is limited to the following:
 - (1) Those prescribed, with or without fluorides, for children under 3 years of age.
 - (2) Those prescribed for prenatal use.
- (f) Payment to a pharmacy for prescriptions dispensed to a recipient in either a skilled nursing facility, an intermediate care facility or an intermediate care

facility for the mentally retarded shall be limited to one dispensing fee for each drug dispensed within a 30-day period.

Authority

The provisions of this § 1121.53 amended under sections 201, 403, 403.1 and 443.4 of the Public Welfare Code (62 P. S. §§ 201, 403, 403.1 and 443.4).

Source

The provisions of this § 1121.53 amended January 16, 1987, effective March 1, 1987, 17 Pa.B. 261; amended December 14, 1990, effective January 11, 1991, 20 Pa.B. 6167; amended August 2, 1991, effective immediately and apply retroactively to July 1, 1989, 21 Pa.B. 3420; amended December 11, 1992, effective January 1, 1993, 22 Pa.B. 5995; amended September 22, 1995, effective October 1, 1995, 25 Pa.B. 3978; amended August 5, 2005, effective August 10, 2005, 35 Pa.B. 4309; amended April 13, 2012, effective April 14, 2012, 42 Pa.B. 2015. Immediately preceding text appears at serial pages (351424) and (312947) to (312949).

(Editor's Note: This regulation was promulgated under section 6(b) of the Regulatory Review Act (71 P. S. § 745.6(b)).)

Cross References

This section cited in 55 Pa. Code § 1121.11 (relating to types of services covered); 55 Pa. Code § 1121.51 (relating to general payment policy); 55 Pa. Code § 1121.52 (relating to payment conditions for various services); 55 Pa. Code § 1121.54 (relating to noncompensable services and items); and 55 Pa. Code § 1121.56 (relating to drug cost determination).

§ 1121.54. Noncompensable services and items.

Payment will not be made to a pharmacy for the following services and items:

- (1) Drugs and other items prescribed for obesity, appetite control or other similar or related habit altering tendencies. Drugs which have been cleared for use in the treatment of hyperkinesia in children and primary and secondary narcolepsy due to structural damage of the brain are compensable if the physician indicates the diagnosis on the original prescription.
- (2) Nonlegend drugs in the form of troches, lozenges, throat tablets, cough drops, chewing gum, mouthwashes and similar items.
- (3) Pharmaceutical services provided to a hospitalized person.
- (4) Drugs and devices classified as experimental by the FDA or whose use is classified as experimental by the FDA.
- (5) Drugs and devices not approved by the FDA or whose use is not approved by the FDA.
- (6) Placebos.
- (7) Legend and nonlegend soaps, cleansing agents, dentifrices, mouthwashes, douche solutions, diluents, ear wax removal agents, deodorants, liniments, antiseptics, irrigants and other personal care and medicine chest items.
- (8) Compounded prescriptions when one of the following applies:
 - (i) Compensable items are used in less than therapeutic quantities.
 - (ii) Noncompensable items are compounded.

(9) Nonlegend drugs not listed in § 1121.53(d) (relating to limitations on payment).

(10) Drugs prescribed in conjunction with sex reassignment procedures or other noncompensable procedures.

(11) The following items when prescribed for recipients in a skilled nursing facility, an intermediate care facility or an intermediate care facility for the mentally retarded:

- (i) Intravenous solutions.
- (ii) Noncompensable drugs and items as specified in this section.
- (iii) The following nonlegend drugs:
 - (A) Analgesics.
 - (B) Antacids.
 - (C) Antacids with simethicone.
 - (D) Cough—cold preparations.
 - (E) Contraceptives.
 - (F) Laxative and stool softeners.
 - (G) Ophthalmic preparations.
 - (H) Diagnostic agents.
- (iv) Legend laxatives.

(12) Items prescribed or ordered by a prescriber who has been barred or suspended from participation in the MA Program. The Department will periodically send pharmacies a list of the names of suspended, terminated or reinstated practitioners and the dates of the various actions. Pharmacies are responsible for checking this list before filling prescriptions.

(13) Prescriptions or orders filled by a pharmacy other than the one to which a recipient has been restricted under § 1101.91 (relating to recipient misutilization and abuse). The Department will issue special medical services eligibility cards to restricted recipients indicating the name of the pharmacy to which the recipient is restricted. Pharmacies are responsible for checking the recipient's medical services eligibility card before filling the prescription.

(14) DESI drugs and identical, similar or related products or combinations of these products.

(15) A pharmaceutical service for which payment is available from another public agency or another insurance or health program except for those drugs prescribed through the county mental health/mental retardation programs as specified in § 1121.51 (relating to general payment policy).

(16) FDA approved pharmaceutical products whose indicated use is not to treat or manage a medical condition, illness or disorder.

(17) Legend and nonlegend pharmaceutical products distributed by a company that has not entered into a National rebate agreement with the Federal government as provided under section 4401 of OBRA '90, except for those specific drug products authorized by the Federal government as essential to the health of an MA recipient. The Department will issue a special list comprised

of those companies that signed rebate agreements with the Federal government and those products authorized as essential to the health of an MA recipient. Pharmacies are responsible for checking the list before filling the prescription.

(18) Legend and nonlegend cough and cold preparations, except when prescribed for MA recipients under 21 years of age.

(19) Erectile dysfunction drugs unless used for an FDA approved indication other than for the treatment of sexual or erectile dysfunction.

Authority

The provisions of this § 1121.54 amended under sections 201(2), 403(b) and 403.1 of the Public Welfare Code (62 P. S. §§ 201(2), 403(b) and 403.1).

Source

The provisions of this § 1121.54 amended January 16, 1987, effective March 1, 1987, 17 Pa.B. 261; amended January 24, 1992, effective April 1, 1991, for the Manufacturers' Rebate Program and September 1, 1991 for the pharmacy dispensing fee increase, 22 Pa.B. 361; amended December 11, 1992, effective January 1, 1993, 22 Pa.B. 5995; amended April 13, 2012, effective April 14, 2012, 42 Pa.B. 2015. Immediately preceding text appears at serial pages (312949) to (312952).

Cross References

This section cited in 55 Pa. Code § 1121.51 (relating to general payment policy).

§ 1121.55. Method of payment.

(a) The Department will pay a pharmacy for a compensable legend and non-legend drug (after deducting the applicable copayment amount, as described in § 1101.63(b) (relating to payment in full)), the lowest of the following amounts:

(1) The EAC for the drug, multiplied by the number of units dispensed, plus a \$2 dispensing fee.

(2) The State MAC for the drug, multiplied by the number of units dispensed, plus a \$2 dispensing fee.

(3) The provider's usual and customary charge to the general public.

(4) For MA recipients with a pharmacy benefit resource which is a primary third party payer to MA, the lower of the following amounts:

(i) The EAC for the drug, multiplied by the number of units dispensed, plus a \$0.50 dispensing fee.

(ii) The State MAC, multiplied by the number of units dispensed, plus a \$0.50 dispensing fee.

(b) The Department will pay a pharmacy for a compensable compounded prescription at the lower of the cost of all ingredients plus a \$3 dispensing fee or the provider's usual and customary charge to the general public. For MA recipients with a pharmacy benefit resource which is a primary third party payer to MA, the dispensing fee shall be \$0.50.

(c) The provider shall bill the Department at its usual and customary charge to the general public.

Authority

The provisions of this § 1121.55 amended under sections 201, 403, 403.1 and 443.4 of the Public Welfare Code (62 P. S. §§ 201, 403, 403.1 and 443.4).

Source

The provisions of this § 1121.55 amended August 10, 1984, effective September 1, 1984, 14 Pa.B. 2926; amended January 16, 1987, effective March 1, 1987, 17 Pa.B. 261; amended December 14, 1990, effective January 11, 1991, 20 Pa.B. 6167; amended January 24, 1992, effective April 1, 1991, for the Manufacturers' Rebate Program and September 1, 1991 for the pharmacy dispensing fee increase, 22 Pa.B. 361; amended September 22, 1995, effective October 1, 1995, 25 Pa.B. 3978; amended April 13, 2012, effective April 14, 2012, 42 Pa.B. 2015. Immediately preceding text appears at serial page (312952).

(Editor's Note: This regulation was promulgated under section 6(b) of the Regulatory Review Act (71 P. S. § 745.6(b)).)

Cross References

This section cited in 6 Pa. Code § 22.11 (relating to general payment principles); 49 Pa. Code § 27.505 (relating to repositories); and 55 Pa. Code § 1121.51 (relating to general payment policy).

§ 1121.56. Drug cost determination.

(a) The Department will base its drug cost for compensable legend and non-legend drugs on the lower of:

(1) The EAC established by the Department.

(i) For brand name drugs, the EAC is established by the Department as one of the following:

(A) The lowest WAC listed for the drug in available Nationally recognized pricing services, plus 3.2%.

(B) If WAC data are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 14%.

(C) If both WAC and AWP cost data are available for the drug from a Nationally recognized pricing service, the lower of the two amounts.

(ii) For generic drugs, the EAC is established by the Department as one of the following:

(A) The lowest WAC listed for the drug in available Nationally recognized pricing services.

(B) If WAC data are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 25%.

(C) If both WAC and AWP cost data are available for the drug from a Nationally recognized pricing service, the lower of the two amounts.

(2) The State MAC established by the Department.

(b) The Department will update the EAC for individual drugs at least on a monthly basis as it appears in available Nationally recognized pricing services.

(c) CMS establishes lists that identify and set Federal upper limits for CMS multisource drugs and provides the listing of these drugs and revisions to the list to the Department through Medicaid manual transmittals on a periodic basis.

(d) The Department will determine the State MAC by one of the following methods:

(1) For multisource drugs, the Department will set the State MAC at the lower of the following:

(i) The upper payment limit established by the CMS.

(ii) Provided that the generic product is available at the price established by the Department from at least two wholesalers:

(A) If the generic product is available from more than one manufacturer, the base price of 150% of the lowest acquisition cost for the generic product, unless 150% of the lowest acquisition cost is not at least 120% of the second lowest acquisition cost, in which case the base price will be set at 120% of the second lowest acquisition cost.

(B) If the generic product is available from only one manufacturer, the base price is 120% of the acquisition cost for the generic product.

(2) For disposable insulin syringes, the Department will set the State MAC at the amount listed in the MA Program Fee Schedule.

(e) The Department will update the State MAC:

(1) If the State MAC for a multisource drug is set at the Federal upper payment limit established by CMS, the Department will apply the Federal upper limits for CMS multisource drugs to be effective on the date established by CMS and will describe the update to each pharmacy enrolled in the MA Program when it is available.

(2) The Department will apply the price for all other State MAC multisource drugs every 3 months, and will distribute the update to each pharmacy enrolled in the MA Program.

(f) With the exception of the CMS multisource drugs, the Department will make further additions to the list of State MAC drugs after consultation with the Medical Assistance Advisory Committee as to whether the application of a State MAC is cost effective to the Department for a particular multisource drug. The Department will add the CMS multisource drugs to the State MAC list effective as of the effective date established by CMS.

(g) With the exception of disposable insulin syringes, the State MAC does not apply if the conditions are met as described in § 1121.53(b)(1) and (2) (relating to limitations on payment).

(h) The most common package size for the purposes of determining the product cost is one of the following:

(1) For capsules, tablets and liquids available in breakable package sizes:

(i) The listed package size if only one package size is listed.

(ii) The 100 or pint package size if more than one package size is listed.

(iii) The next smaller package size from the 100 or pint size, excluding a drug company's unit-dose package size, if more than one package size is listed other than the 100 or pint package size.

(iv) The package size closest to the 100 or pint package size, excluding a drug company's unit-dose package size, if the next smaller package is the unit-dose package size.

(2) The listed package size for all dosage forms available for all nonlegend drug products.

(3) The smallest package size for all dosage forms available in nonbreakable packages.

Authority

The provisions of this § 1121.56 amended under sections 201, 403, 403.1 and 443.4 of the Public Welfare Code (62 P. S. §§ 201, 403, 403.1 and 443.4).

Source

The provisions of this § 1121.56 amended January 16, 1987, effective March 1, 1987, 17 Pa.B. 261; amended December 14, 1990, effective January 11, 1991, 20 Pa.B. 6167; amended September 22, 1995, effective September 23, 1995, 25 Pa.B. 3978; amended August 5, 2005, effective August 10, 2005, 35 Pa.B. 4309; amended August 19, 2005, effective August 22, 2005, 35 Pa.B. 4727; corrected August 26, 2005, effective August 22, 2005, 35 Pa.B. 4309; amended April 13, 2012, effective April 14, 2012, 42 Pa.B. 2015. Immediately preceding text appears at serial pages (312953) to (312954) and (337485).

Notes of Decisions

The deduction provisions of section 9413.61 of the MA Manual have been replaced by the current regulations concerning prescription reimbursement to pharmacies, therefore the remedy for improper distribution under the prior scheme is the difference between the amount of reimbursement under that scheme and the amount of reimbursement had it been calculated under the current scheme under this section. *Brog Pharmacy v. Department of Public Welfare*, 487 A.2d 49 (Pa. Cmwlth. 1985).

(Editor's Note: This regulation was promulgated under section 6(b) of the Regulatory Review Act (71 P. S. § 745.6(b)).)

Cross References

This section cited in 55 Pa. Code § 1121.51 (relating to general payment policy).

UTILIZATION REVIEW

§ 1121.71. Scope of claims review procedures.

Claims submitted for payment under the MA Program are subject to the utilization review procedures established in Chapter 1101 (relating to general provisions) and § 1121.42(1) (relating to ongoing responsibilities of providers).

ADMINISTRATIVE SANCTIONS**§ 1121.81. Provider misutilization.**

(a) A provider determined to have billed for services inconsistent with MA Program regulations, to have provided services outside the scope of customary standards of pharmaceutical practice, or to have otherwise violated the standards in the provider agreement, is subject to the sanctions described in Chapter 1101 (relating to general provisions).

(b) Where a provider is subject to subsection (a) or § 1101.77 (relating to enforcement actions by the Department), the pharmacist responsible for the violations, the owner of the provider at the time of the violation and a person owning 5% or more of shares of stock in the provider at the time of the violation shall be subject to preclusion from indirect participation in the MA Program for the same period as a sanction against the provider. No provider may participate or be enrolled in the MA Program while owned or operated by a person precluded from indirect participation. Ownership includes but is not limited to ownership of 5% or more of the corporate stock of the provider if the provider is incorporated.

Notes of Decisions

A provider pharmacy which permitted an unlicensed pharmacist's assistant to fill and dispense prescriptions "provided services outside the scope of customary standards of pharmaceutical practice" subsection (a). *Girard Prescription Center v. Department of Public Welfare*, 496 A.2d 83 (Pa. Cmwlth. 1985); appeal granted 503 A.2d 930 (Pa. 1986).

There is no element of scienter in this section, which permits the Department of Public Welfare to impose sanctions on a provider pharmacy which has "provided services outside the scope of customary standards of pharmaceutical practice." *Girard Prescription Center v. Department of Public Welfare*, 496 A.2d 83 (Pa. Cmwlth. 1985).

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