

## **CABINET FOR HEALTH AND FAMILY SERVICES**

### **Department for Medicaid Services**

#### **Division of Policy and Operations**

##### **(Amendment)**

#### **907 KAR 23:020. Reimbursement for outpatient drugs.**

RELATES TO: KRS 205.5510 to 205.5520, 205.560, 205.561, 205.5631, 205.5632, 205.5634, 205.5636, 205.5638, 205.5639, 205.622, 205.6316(4), 217.015, 42 C.F.R. 440.120, 447.45, 447.500 - 447.520, 42 U.S.C. 256b, 1396a - 1396d, 1396r-8

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.5514(1)(b), 205.560, 205.561(2), 205.6316(4), 205.647(5), 42 U.S.C. 1396a(a)(30), 42 U.S.C. 1396r-8

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. KRS 205.561(2) and 205.6316(4) require the department to promulgate an administrative regulation to establish the professional dispensing fee for covered drugs. This administrative regulation establishes the Medicaid Program reimbursement requirements, including the professional dispensing fee, for covered outpatient drugs dispensed to all enrolled Medicaid recipients.

Section 1. Reimbursement. Reimbursement to a pharmacy or medical provider participating in the Medicaid Program for a covered outpatient drug provided to an eligible recipient shall be determined in accordance with the requirements established in this section.

- (1) A rebate agreement in accordance with 42 U.S.C. 1396r-8(a) shall be signed by the drug manufacturer, or the drug shall be provided based on an exemption from the rebate requirement established by 907 KAR 23:010, Section 5(3).
- (2) A pharmacy claim shall meet the point of sale (POS) requirements for services in accordance with 907 KAR 1:673.
- (3) Reimbursement shall not be made for more than one (1) prescription to the same recipient during the same time period for a drug with the same:
  - (a) National Drug Code (NDC); or
  - (b) Drug or active ingredient name, strength, and dosage form.
- (4) A timely claim payment shall be processed in accordance with 42 C.F.R. 447.45.
  - (a) In accordance with 42 C.F.R. 447.45, a claim shall be submitted to the department within twelve (12) months of the date of service.
  - (b) The department shall not reimburse for a claim submitted to the department after twelve (12) months from the date of service unless the claim is for a drug dispensed to an individual who was retroactively determined to be eligible for Medicaid.
  - (c) The department shall not reimburse a claim for a drug dispensed to an individual who was retroactively determined to be eligible for Medicaid after 365 days have lapsed from the date that the department issued the notice of retroactive eligibility.
- (5) Reimbursement shall be denied if:
  - (a) The recipient is ineligible on the date of service;
  - (b) The drug is excluded from coverage in accordance with 907 KAR 23:010; or
  - (c) Prior authorization is required by the department and the request for prior authorization has not been approved prior to dispensing the drug, except in an emergency supply situation.
- (6) Pursuant to KRS 205.622, prior to billing the department, a provider shall submit a bill to a third party payer if the provider has knowledge that the third party payer may be

liable for payment.

(a) If a provider is aware that a Medicaid recipient has additional insurance or if a recipient indicates in any manner that the recipient has additional insurance, the provider shall submit a bill to the third party in accordance with KRS 205.622.

(b) A provider who is aware that a recipient may have other insurance, but the other insurance is not identified on the medical assistance identification card or by the recipient, shall notify the department's fiscal agent of the potential third-party liability.

(7) There shall be no copayment or cost-sharing for an outpatient drug.

(8) If a payment is made for a drug that was not administered or dispensed in accordance with 907 KAR 23:010 or the payment was not appropriately reimbursed as required by this administrative regulation, the provider shall refund the amount of the payment to the department or the department may, at its discretion, recoup the amount of the payment.

(9) Adherence to the requirements established in this section shall be monitored through an on-site audit, post payment review of the claim, a computer audit, or an edit of the claim.

## Section 2. Reimbursement Methodology.

(1) Drug cost shall be determined in the pharmacy program using drug pricing and coding information obtained from nationally recognized comprehensive drug data files with pricing based on the actual package size utilized.

(2) Lowest of Logic. Except as provided in Section 4 of this administrative regulation, covered outpatient drug cost shall be reimbursed at the lowest of the:

(a) National Average Drug Acquisition Cost or NADAC, plus the professional dispensing fee, as established in Section 3;

(b) Wholesale acquisition cost or WAC, plus the professional dispensing fee, as established in Section 3;

(c) Federal upper limit or FUL, plus the professional dispensing fee, as established in Section 3;

(d) Maximum allowable cost or MAC, plus the professional dispensing fee, as established in Section 3; or

(e) The provider's usual and customary charge to the public, as identified by the claim charge.

(3) A clotting factor shall be reimbursed via the lowest of logic established in subsection (2) of this section and shall include the Average Sales Price plus six (6) percent, plus the professional dispensing fee, as established in Section 3.

(4) Pursuant to KRS 205.5510 to 205.5520:

(a) Reimbursement methodologies for the managed care population shall be subject to the terms of the awarded contract to administer the single pharmacy benefits manager or PBM for the managed care population.

(b) The single PBM for the managed care population shall not discriminate against 340B contract pharmacies via any reimbursement methodologies utilized.

## Section 3. Professional Dispensing Fee.

(1) Effective April 1, 2017, the professional dispensing fee for a covered outpatient drug prescribed by an authorized prescriber and dispensed by a participating pharmacy provider in accordance with 907 KAR 23:010, and pursuant to a valid prescription shall be \$10.64 per pharmacy provider per recipient per drug per month.

(2) The professional dispensing fee for a compounded drug shall be \$10.64 per pharmacy provider per recipient per drug reimbursed up to three (3) times every thirteen (13) days.

(3)

(a) As warranted by the applicable standard of care, the professional dispensing fee for a qualifying drug that is dispensed for the treatment of a substance use disorder shall

be \$10.64 per pharmacy provider per recipient per drug reimbursed once every seven (7) days.

(b) Any additional dispenses after the first dispensing shall be warranted by the applicable standard of care.

#### Section 4. Reimbursement Limitations.

(1) Emergency supply. Dispensing of an emergency supply of a drug shall be made outside of the prescriber's normal business hours and as permitted in accordance with 907 KAR 23:010.

(2) Partial fill. If the dispensing of a drug results in partial filling of the quantity prescribed, including an emergency supply, reimbursement for the drug ingredient cost for the actual quantity dispensed in the partial fill and the completion fill for the remainder of the prescribed quantity shall:

(a) Utilize the lowest of logic established by Section 2 of this administrative regulation; and

(b) Include payment of only one (1) professional dispensing fee, which shall be paid at the time of the completion fill.

(3) Maintenance drugs. The department shall not reimburse for a refill of a maintenance drug prior to the end of the dispensing period established by 907 KAR 23:010 unless the department determines that it is in the best interest of the recipient.

(4) For a nursing facility resident meeting Medicaid nursing facility level of care criteria, and in accordance with 201 KAR 2:190 and 902 KAR 55:065, an unused drug paid for by Medicaid shall be returned to the originating pharmacy and the department shall be credited for the drug ingredient cost.

(5) For a Medicaid recipient participating in a hospice program, payment for a drug shall be in accordance with 907 KAR 1:340.

(6) Physician administered drugs (PAD).

(a) Federal rebate required. Only covered PAD products that are federally rebateable pursuant to a manufacturer rebate agreement shall be reimbursed.

(b) Non-340B purchased PAD. Reimbursement for drug cost for a drug administered by a physician or the physician's authorized agent in an office or outpatient clinic setting, not purchased through the 340B Program, and submitted for reimbursement as a medical benefit shall be reimbursed only for the drug cost by the lowest of logic required by Section 2 of this administrative regulation, which shall include the average sales price (ASP) plus six (6) percent. A professional dispensing fee shall not be paid for PAD.

(c) 340B purchased PAD. For a drug purchased through the 340B Program and administered by a physician or the physician's authorized agent in an office or outpatient clinic setting, and submitted for reimbursement as a medical benefit, the lowest of logic required by Section 2 of this administrative regulation shall include the 340B ceiling price. The covered entity shall bill no more than the actual 340B acquisition cost. A professional dispensing fee shall not be paid for PAD.

#### Section 5. 340B Pharmacy Transactions for Fee-For-Service.

(1) A pharmacy dispensing drugs purchased through the 340B Program pursuant to a 340B eligible prescription from a covered entity shall bill the department no more than the actual 340B acquisition cost, plus the professional dispensing fee.

(2) For a 340B purchased drug dispensed by a pharmacy, the lowest of logic shall include the 340B ceiling price.

(3) A drug dispensed by a 340B contract pharmacy shall not be eligible as a 340B transaction and shall be reimbursed in accordance with the lowest of logic as required by Section 2 of this administrative regulation plus the professional dispensing fee.

Section 6. 340B Pharmacy Transactions for Managed Care.

(1) A pharmacy dispensing drugs purchased through the 340B Program pursuant to a 340B eligible prescription from a covered entity shall bill the department and be reimbursed pursuant to Section 2 of this administrative regulation.

(2) A 340B covered entity pharmacy shall notify the department on its own behalf and on behalf of any contracted pharmacy if it intends to use 340B drugs to fill prescriptions for qualified pharmacy claims within the managed care Medicaid program.

(3)

(a) A covered entity that intends to use 340B drugs to fill prescriptions for qualified pharmacy claims shall submit a complete and accurate "Kentucky Medicaid 340B Participation Form".

1. A form shall be filed by the fifteenth (15th) of the last month of a quarter in order to be effective for that quarter. A form that is submitted later than the fifteenth (15th) of the last month of a quarter shall be effective for the following quarter and until revoked.

2. The form shall be effective until revoked pursuant to subsection (4) of this section.

(b) Any covered entity that no longer intends to participate and use 340B drugs to fill prescriptions for qualified pharmacy claims shall submit a complete and accurate "Kentucky Medicaid 340B Nonparticipation Form".

(4) All submissions shall be via electronic mail to an email account designated on the Kentucky Pharmacy Program website located at: <https://chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx>

(5) The following entities, as relevant, shall review each previous quarter's eligible pharmacy claims:

(a) The covered entity, or the entity's designated claims administrator; and

(b) The contract pharmacy, or the entity's designated claims administrator.

Section 7. The maximum allowable cost, or MAC, shall be determined by taking into account each drug's cost, rebate status (non-rebateable or rebateable) in accordance with 42 U.S.C. 1396r-8(a), marketplace status (obsolete, terminated, or regional availability), equivalency rating (A-rated), and relative comparable pricing. Other factors considered shall include clinical indications of drug substitution, utilization, and availability in the marketplace.

(1) Drug pricing resources used to compare estimated acquisition costs for multiple-source drugs shall include comprehensive data files maintained by a vendor under contract to the department, such as:

(a) NADAC as published by CMS;

(b) WAC, manufacturer's price list, or other nationally recognized sources;

(c) The Average Manufacturers Price for 5i Drugs as reported by CMS;

(d) ASP as published by CMS;

(e) Nationally recognized drug file vendors approved for use at a federal level and that have been approved by the department;

(f) Pharmacy providers; or

(g) Wholesalers.

(2) The department shall maintain a current listing of drugs and their corresponding MAC prices accessible through the department's pharmacy Web page.

(3) The process for a pharmacy provider to appeal a MAC price for a drug shall be as established in this subsection.

(a) The pharmacy provider shall email or fax a completed Kentucky Medicaid MAC Price Research Request Form to Kentucky's authorized agent in accordance with the instructions on the form.

- (b) An appeal of a MAC price for a drug shall be investigated and resolved within three (3) business days.
- (c) If available, the provider shall be supplied with the name of one (1) or more manufacturers who have a price comparable to the MAC price.
- (d) The MAC price and effective date of that price shall be adjusted accordingly, retroactive to the date of service for the claim in question, if:
  - 1. It is determined that a manufacturer does not exist in the price range referenced in paragraph (c) of this subsection; or
  - 2. The provider is able to document that despite reasonable efforts to obtain access, he or she does not have access to the one (1) or more manufacturers supplied to the provider.
- (e) If an adjusted MAC price becomes effective, the provider shall be informed that the claim may be rebilled for the price adjustment.

Section 8. Federal Approval and Federal Financial Participation. The department's reimbursement for services pursuant to this administrative regulation shall be contingent upon:

- (1) Receipt of federal financial participation for the reimbursement; and
- (2) Centers for Medicare and Medicaid Services' approval for the reimbursement.

Section 9. Incorporation by Reference.

- (1) The following documents are incorporated by reference:
  - (a) "Kentucky Medicaid MAC Price Research Request Form", 2012;.
  - (b) "Kentucky Medicaid 340B Participation Form", 2022.
  - (c) "Kentucky Medicaid 340B Nonparticipation Form", 2022.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at:
  - (a) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky, Monday through Friday, 8:00 a.m. to 4:30 p.m.; or
  - (b) Online at the department's Web site at <https://chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx>.

*LISA D. LEE, Commissioner*

*ERIC FRIEDLANDER, Secretary*

APPROVED BY AGENCY: May 20, 2022

FILED WITH LRC: June 1, 2022 at 8:30 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on August 22, 2022, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by August 15, 2022, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until August 31, 2022. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

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