

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Administration and Financial Management

4 (Amended After Comments)

5 907 KAR 1:018. Reimbursement for drugs.

6 RELATES TO: KRS 205.560, 205.561, 205.5631, 205.5632, 205.5634, 205.5636,
7 205.5638, 205.5639, 205.6316(4), 217.015, 311.550, 311.560, 42 C.F.R. 440.120,
8 447.331, 447.332, 447.333, 42 U.S.C. 256b, 1396a-d

9 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560,
10 205.561(2), 205.6316(4), 42 USC 1396a(a)(30), 42 USC 1396r-8, ~~2005 Ky. Acts ch. 99~~

11 NECESSITY, FUNCTION, AND CONFORMITY: ~~[2005 Ky. Acts ch. 99 reorganized~~
12 ~~the Cabinet for Health Services and placed the Department for Medicaid Services and~~
13 ~~the Medicaid Program under the Cabinet for Health and Family Services.]~~ The Cabinet
14 for Health and Family Services, Department for Medicaid Services has responsibility to
15 administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by adminis-
16 trative regulation, to comply with any requirement that may be imposed or opportunity
17 presented by federal law to qualify for federal Medicaid funds~~[for the provision of medi-~~
18 ~~cal assistance to Kentucky's indigent citizenry]~~. KRS 205.561(2) and 205.6316(4) re-
19 quire the department to promulgate an administrative regulation to establish a dispens-
20 ing fee for prescriptions. This administrative regulation establishes the Medicaid pro-
21 gram reimbursement policies for drugs dispensed to Medicaid recipients who are not

1 enrolled with a managed care organization~~[method for determining reimbursement for~~
2 ~~drugs through the Medicaid Outpatient Pharmacy Program and the dispensing fees].~~

3 Section 1. Definitions. (1) "A-rated generic product" means a product that the FDA
4 has found to be bioequivalent.

5 (2)~~["Average wholesale price" or "AWP" means the average wholesale price pub-~~
6 ~~lished in a nationally recognized comprehensive drug data file for which the department~~
7 ~~has contracted.~~

8 ~~(3)~~ "Department" means the Department for Medicaid Services or its designated
9 agent.

10 ~~(3)~~~~(4)~~ "Direct price" means the estimated acquisition cost for which a retailer can
11 purchase a drug product directly from the manufacturer as listed in a nationally-
12 recognized comprehensive drug data file for which the department has contracted.

13 ~~(4)~~~~(5)~~ "Dispensing fee" means a professional fee paid to reimburse a pharmacy for
14 costs associated with the dispensing of a prescribed drug.

15 (5) "Federal financial participation" is defined by 42 CFR 400.203.

16 (6) "Federal upper limit" or "FUL" means the maximum federal financial participation
17 available toward reimbursement for a given drug dispensed to a Medicaid recipient.

18 ~~(7)~~~~(6)~~ "Food and Drug Administration" or "FDA" means the Food and Drug Adminis-
19 tration of the United States Department of Health and Human Services.

20 (8) "State maximum allowable cost" means the maximum amount established by the
21 department that the department shall reimburse for a drug.

22 ~~(9)~~~~(7)~~ "Weighted majority of volume purchase" means a calculation used in deter-
23 mining a state maximum allowable cost or MAC that is based on market share.

1 ~~(10)~~~~(8)~~ "Wholesale acquisition cost" or "WAC" means the estimated acquisition cost
2 for the wholesaler as listed in a nationally-recognized comprehensive drug data file for
3 which the department has contracted.

4 Section 2. Reimbursement. (1) Drug copayment requirements and provisions shall be
5 as established in 907 KAR 1:604.

6 (2) The department:

7 (a) May establish a state maximum allowable~~[maximum-allowable]~~ cost for a drug:

8 1. If two (2) or more A-rated therapeutically-equivalent, multisource, noninnovator
9 drugs with a significant cost difference exist for the given drug; and

10 2. By reviewing the pricing sources WAC~~[AWP, WAC,]~~ and direct price for the drug
11 as identified in a nationally-recognized comprehensive drug data file for which the de-
12 partment has contracted and utilizing the weighted majority of volume purchased. ~~[For~~
13 ~~example, if for a given drug there are two (2) therapeutically-equivalent drugs with one~~
14 ~~(1) priced at five (5) dollars per pill and possessing thirty (30) percent of the market~~
15 ~~share and the other priced at one (1) dollar per pill and possessing seventy (70) percent~~
16 ~~of the market share, the department shall factor in the market share in determining the~~
17 ~~state MAC price rather than simply averaging the two (2) prices]; and~~

18 (b) Shall maintain a current listing of drugs and their corresponding state maximum
19 allowable ~~[maximum-allowable]~~ costs via a link from the department web site located at
20 the following address:

21 <http://www.chfs.ky.gov/dms>.

22 (3) An appeal of a state maximum allowable~~[maximum-allowable]~~ cost price for a
23 drug shall be as follows:

1 (a)[4.] The provider shall email or fax a completed Kentucky Medicaid MAC Price Re-
2 search Request Form (which is available at the department's website which is
3 <http://www.chfs.ky.gov/dms>) to Magellan Medicaid Administration in accordance with
4 the instructions on the form.["~~MAC Price Inquiries and Research Request Form~~" (which
5 is available at the department and at the Web site address:
6 ~~<http://kentucky.fhsc.com/providers/documents.asp>, by clicking on "MAC Price Inquires~~
7 ~~and Research Request Form or via the specific Web site address:~~
8 ~~http://kentuckyfhsc.com/Downloads/providers/KYRx_MACResearchRequestForm.pdf) to~~
9 ~~First Health Services Corporation. The email address is rebate@fhsc.com and the fax~~
10 ~~number is 804-217-7911; or~~

11 2. ~~The provider shall contact the First Health Services Corporation technical call cen-~~
12 ~~ter at 1-800-432-7005 and provide information regarding the appeal including the na-~~
13 ~~tional drug code for the drug in question;]~~

14 (b) An appeal of a state maximum allowable[~~maximum-allowable~~] cost price for a
15 drug shall be investigated and resolved within three (3) business days;

16 (c) If available, the provider shall be supplied with the name of one (1) or more manu-
17 facturers who have a price comparable to the state maximum allowable[~~maximum-~~
18 ~~allowable~~] cost price;

19 (d) The state maximum allowable[~~maximum-allowable~~] cost price and effective date
20 of that price shall be adjusted accordingly, retroactive to the date of service for the state
21 maximum allowable[~~maximum-allowable~~] cost price prescription in question, if:

22 1. It is determined that no manufacturer exists in the price range referenced in para-
23 graph (c) of this subsection; or

1 2. The provider is able to document that despite reasonable efforts to obtain access,
2 he or she does not have access to the one (1) or more manufacturers supplied to the
3 provider; and

4 (e) When the change in state maximum allowable~~maximum allowable~~ cost price for
5 a price that is adjusted becomes effective, the provider shall be informed that the claim
6 may be rebilled for the price adjustment.

7 (4) Reimbursement to a pharmacy participating in the Medicaid Program for a drug
8 listed in the Kentucky Medicaid Outpatient Drug List established in 907 KAR 1:019 and
9 provided to an eligible recipient shall be determined in accordance with the require-
10 ments established in this subsection.

11 (a) An appropriate rebate agreement shall be signed by the drug manufacturer or the
12 drug shall be provided based on a prior authorized exemption from the rebate require-
13 ment in accordance with 907 KAR 1:019.

14 (b) Drug costs shall be determined in the Pharmacy Program using drug pricing and
15 coding information obtained from a nationally-recognized comprehensive drug data file
16 for which the department has contracted with pricing based on the actual package size
17 utilized.

18 (c) Reimbursement for a drug shall be the lesser of:

19 1. The federal upper limit, if one (1) exists, plus a dispensing fee and, if applicable, a
20 unit dose addition;

21 2. The state maximum allowable~~maximum allowable~~ cost, if one (1) exists, plus a
22 dispensing fee and, if applicable, a unit dose addition;

23 3. The estimated acquisition cost (EAC) which shall:

- 1 a. For a generic drug, equal the WAC plus 3.2 [~~AWP minus fourteen (14)~~] percent,
2 plus a dispensing fee and, if applicable, a unit dose addition; and
- 3 b. For a brand name drug, equal the WAC plus two (2) [~~AWP minus fifteen (15)~~] per-
4 cent, plus a dispensing fee and, if applicable, a unit dose addition;
- 5 4. The usual and customary billed charge.
- 6 (d) Reimbursement for the dispensing of an emergency supply of a drug shall be:
- 7 1. Made only outside normal business hours of the department's Drug Prior Authori-
8 zation office and as permitted in accordance with 907 KAR 1:019, Section 4; and
- 9 2. The lesser of:
- 10 a. The federal upper limit, if one (1) exists, plus the dispensing fee for the prescription
11 and, if applicable, a unit dose addition;
- 12 b. The state maximum allowable [~~maximum-allowable~~] cost, if one (1) exists, plus a
13 dispensing fee and, if applicable, a unit dose addition;
- 14 c. The estimated acquisition cost (EAC), which shall:
- 15 (i) For a generic drug, equal the WAC plus 3.2 [~~AWP minus fourteen (14)~~] percent,
16 plus a dispensing fee and, if applicable, a unit dose addition; and
- 17 (ii) For a brand name drug, equal the WAC plus two (2) [~~AWP minus fifteen (15)~~] per-
18 cent, plus a dispensing fee and, if applicable, a unit dose addition;
- 19 d. The usual and customary billed charge.
- 20 (e) If the dispensing of an emergency supply results in partial filling of the quantity or
21 amount prescribed, reimbursement for the partial filling of the remainder of the prescrip-
22 tion shall utilize the methodology specified in paragraph (c) of this subsection, except
23 that only one (1) dispensing fee shall be allowed for the combined partial fill and subse-

1 quent completion fill.

2 (f) Reimbursement shall be denied if:

3 1. The recipient is ineligible on the date of service;

4 2. The drug is excluded from coverage in accordance with 907 KAR 1:019, Section 3;

5 or

6 3. Prior authorization is required by the department and **the request for prior autho-**

7 **rization** has not been **submitted[granted]** prior to dispensing of the drug~~[has been de-~~
8 ~~nied or has not been requested]~~.

9 (g) For a nursing facility resident meeting Medicaid nursing facility level of care crite-
10 ria in accordance with 907 KAR 1:022, there shall not be more than one (1) dispensing
11 fee allowed per provider per recipient per drug within a rolling twenty-four (24) day pe-
12 riod unless[:

13 1. The drug is a Schedule II, III, or IV controlled substance or a legend intravenous
14 drug, in which case up to three (3) additional dispensing fees shall be allowed;

15 2. The drug is a nonsolid dosage form, in which case one (1) additional dispensing
16 fee shall be allowed;

17 3. the prescribed dosage has been changed, in which case one (1) additional dis-
18 pensing fee shall be allowed; or

19 4. The department determines that it is in the best interest of the recipient to allow the
20 additional dispensing fee.

21 (h) For a nursing facility resident meeting Medicaid nursing facility level of care crite-
22 ria and if appropriate and in accordance with 201 KAR 2:190 and 902 KAR 55:065, an
23 unused drug, paid for by Medicaid, shall be returned to the originating pharmacy and

1 the department shall be credited for the cost of the drug and the unit dose packaging
2 cost.

3 (i) 1. A maintenance drug shall be dispensed in accordance with 907 KAR 1:019.

4 2. The department shall not reimburse for a refill of a maintenance drug prior to the
5 end of the dispensing period established in 907 KAR 1:019~~[to an outpatient service re-~~
6 ~~ipient, except for an individual receiving supports for community living services, up to a~~
7 ~~ninety-two (92) day supply with only one (1) initial dispensing fee and one (1) refill dis-~~
8 ~~pensing fee allowed within the ninety-two (92) day time period unless the department~~
9 ~~determines that it is in the best interest of the recipient to allow any additional dispensa-~~
10 ~~tions or dispensing fees; and~~

11 3.[2.] For an outpatient service recipient receiving services via the Supports for
12 Community Living Program, there shall not be more than:

13 a. One (1) dispensing fee allowed per drug per calendar month for a drug classified
14 by the Medicaid Program as a maintenance drug unless there is an exception described
15 in clause c of this subparagraph;

16 b. Four (4) dispensing fees allowed per drug within a calendar month for a legend
17 intravenous drug or a Schedule II, III or IV controlled substance; or

18 c.(i) Two (2) dispensing fees allowed per drug within a calendar month for a drug that
19 is a nonsolid dosage form; or

20 (ii) Four (4) dispensing fees allowed per maintenance drug in one (1) month if a pre-
21 scriber requests to prescribe less than a thirty (30) day supply based on medical spe-
22 cialty, best practice standards, and appropriateness of care.

23 (j) For a personal care recipient, there shall not be more than:

1 1. One (1) dispensing fee allowed per drug per calendar month for a drug classified
2 by the Medicaid Program as a maintenance drug unless there is an exception described
3 in subparagraph 3 of this paragraph;

4 2. Four (4) dispensing fees allowed per drug within a calendar month for a legend
5 intravenous drug or a Schedule II, III or IV controlled substance; or

6 3.a. Two (2) dispensing fees allowed per drug within a calendar month for a drug that
7 is a nonsolid dosage form; or

8 b. Four (4) dispensing fees allowed per maintenance drug in one (1) month if a pre-
9 scriber requests to prescribe less than a thirty (30) day supply based on medical spe-
10 cialty, best practice standards, and appropriateness of care.

11 (k) Reimbursement shall not be made for more than one (1) prescription to the same
12 recipient on the same day for a drug with the same:

13 1. National Drug Code (NDC); or

14 2. Generic name, strength, and dosage form.

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

17 (6) A pharmacy claim shall meet the point of sale (POS) requirements for services in
18 accordance with 907 KAR 1:673.

19 (7) If a payment is made for a drug for which there is no authorization as required in
20 accordance with 907 KAR 1:019, the provider shall reimburse the department the
21 amount of the payment.

22 (8)(a) A timely claim payment shall be processed in accordance with 42 C.F.R.
23 447.45.

1 (b) In accordance with 42 CFR 447.45, a claim shall be submitted to the
2 department within twelve (12) months of the date of service.

3 (c)1. The department shall not reimburse for a claim submitted to the depart-
4 ment after twelve (12) months from the date of service unless the claim is for a
5 drug dispensed to an individual who was retroactively determined to be eligible
6 for Medicaid.

7 2. The department shall reimburse for a claim for a drug dispensed to an indi-
8 vidual who was retroactively determined to be eligible for Medicaid for up to 365
9 days from the date that the department issued a letter to the individual informing
10 the individual of Medicaid eligibility.

11 3. The department shall not reimburse for a claim referenced in subparagraph
12 2. of this paragraph after 365 days have lapsed since the department issued the
13 notice of retroactive eligibility.

14 ~~(9) [A claim in which retroactive eligibility is established shall be submitted up~~
15 ~~to twelve (12) months from the issue date noted on the Medicaid recipient's medi-~~
16 ~~cal assistance identification card. If the date of service is greater than twelve (12)~~
17 ~~months old, the claim shall be submitted as a paper claim with a copy of the re-~~
18 ~~troactive medical assistance identification card attached.~~

19 ~~(10)]~~ Pursuant to KRS 205.622, prior to billing the department, a provider shall submit
20 a bill to a third party payer[Medicare] if the provider has knowledge that the third party
21 payer [Medicare] may be liable for payment.

22 (11)(a) If a provider is aware that a Medicaid recipient has additional insurance or if a
23 recipient's~~[(11)(a) If the]~~ medical assistance identification card indicates that the Medi-

1 caid recipient has additional insurance, the provider shall submit a bill to the third party
2 in accordance with KRS 205.622.

3 (b) A provider who is aware that a recipient has other insurance, but no insurance is
4 indicated on the medical assistance identification card, shall notify the department's fis-
5 cal agent of the third-party liability.

6 (12) Adherence to the requirements established in this section shall be monitored
7 through an on-site audit, postpayment review of the claim, a computer audit or an edit of
8 the claim.

9 (13)(a) A pharmacy of a covered entity as defined in 42 U.S.C. 256b which purchas-
10 es drugs through the United States Public Health Service Discount Program in accor-
11 dance with 42 U.S.C. 256b shall bill the department the pharmacy's actual 340B acqui-
12 sition cost for all drugs~~[a drug]~~; and

13 (b) The department shall reimburse the pharmacy's actual 340B acquisition cost for
14 the drug plus a dispensing fee in accordance with Section 3 of this administrative regu-
15 lation.

16 (14) If a covered entity as defined in 42 U.S.C. 256b notifies the United States Office
17 of Pharmacy Affairs that its pharmacy is not included under 42 U.S.C. 256b:

18 (a) The pharmacy shall submit its usual and customary amount for a drug; and

19 (b) The department shall reimburse for a drug in accordance with this section plus a
20 dispensing fee in accordance with Section 3 of this administrative regulation.

21 Section 3. Dispensing Fees. (1) To determine a dispensing fee, the department shall
22 comply with KRS 205.561.

23 (2) Except as provided in subsection (3) of this section and in accordance with KRS

1 205.561, the dispensing fee, unless excluded by Section 2(4)(d) of this administrative
2 regulation, shall be:

3 (a) Five (5) dollars per prescription for a generic drug reimbursed through the Outpa-
4 tient Drug Program if dispensed to an eligible recipient, including an eligible recipient in
5 a nursing facility meeting the nursing facility level of care criteria requirements estab-
6 lished in 907 KAR 1:022; and

7 (b) Four (4) dollars and fifty (50) cents per prescription for a brand name drug reim-
8 bursed through the outpatient drug program if dispensed to an eligible recipient, includ-
9 ing an eligible recipient in a nursing facility meeting the nursing facility level of care crite-
10 ria requirements established in 907 KAR 1:022.

11 (3)(a) For a recipient in a nursing facility meeting the nursing facility level of care cri-
12 teria requirements established in 907 KAR 1:022, a unit dose addition to the usual reim-
13 bursement shall be made for a drug dispensed through the Pharmacy Outpatient Drug
14 Program in the amount of two (2) cents per unit dose for a nonunit dose drug repack-
15 aged in unit dose form by the pharmacist.

16 (b) The unit dose addition shall be paid, as appropriate, even though the usual dis-
17 pensing fee of five (5) dollars for a generic drug or four (4) dollars and fifty (50) cents for
18 a brand name drug is not paid due to monthly limits on dispensing fees or in accordance
19 with Section 2(4)(d) of this administrative regulation.

20 Section 4. Reimbursement to Dispensing Physicians. A participating dispensing phy-
21 sician who practices in a county where a pharmacy is not located shall be reimbursed
22 for the cost of the drug, with the cost computed:

23 (1) As the lesser of:

1 (a) The maximum-allowable cost or estimated acquisition cost established in Section
2 2(4) of this administrative regulation;

3 (b) The physician's usual and customary amount; or

4 (c) The federal upper limit; or

5 (2) In accordance with 907 KAR 3:010 for a free immunization through the Vaccines
6 for Children Program.

7 Section 5. Incorporation by Reference. (1) The "Kentucky Medicaid MAC Price~~[MAC~~
8 ~~Price Inquiries and]~~ Research Request Form", June 18, 2010~~[December 2004]~~ edition,
9 is incorporated by reference.

10 (2) This material may be inspected, copied, or obtained, subject to applicable copy-
11 right law, at the Department for Medicaid Services, 275 East Main Street, Frankfort,
12 Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

907 KAR 1:018

REVIEWED:

Date

Neville Wise, Acting Commissioner
Department for Medicaid Services

APPROVED:

Date

Janie Miller, Secretary
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation Number: 907 KAR 1:018
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Cindy Gray (502) 564-9444 or Stuart Owen (502) 564-4321

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the Medicaid program reimbursement policies for drugs dispensed to Medicaid recipients who are not enrolled with a managed care organization.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the Medicaid program reimbursement policies for drugs dispensed to Medicaid recipients who are not enrolled with a managed care organization.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing the Medicaid program reimbursement policies for drugs dispensed to Medicaid recipients who are not enrolled with a managed care organization.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by establishing the Medicaid program reimbursement policies for drugs dispensed to Medicaid recipients who are not enrolled with a managed care organization.

- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The amendment eliminates average wholesale price (AWP) as a drug pricing component and replaces it with wholesale acquisition cost (WAC.) Wholesale acquisition cost is the list price on drugs for wholesalers and others prior to any rebates or discounts on the drugs. The amendment after comments establishes that the Department for Medicaid Services (DMS) won't reimburse for a prescription if a request for prior authorization was not submitted prior to the dispensing of the drug. The prior amendment established that DMS would not reimburse if prior authorization had not been granted prior to the dispensing of the drug. Additionally, the amendment after comments establishes that a claim associated with an individual who was retroactively determined to be eligible for Medicaid must be submitted within 365 days of DMS notifying the individual of Medicaid eligibility in order for DMS to reimburse for the claim. DMS will not reimburse for a claim submitted after 365 days from the retroactive eligibility notification.
 - (b) The necessity of the amendment to this administrative regulation: The amendment regarding average wholesale price (AWP) is necessary as AWP will no

longer be published by First Databank, Inc. after September 26, 2011. The unavailability of AWP stems in part from the resolution of a civil court case - *New England Carpenters Health Benefits Fund, et al. v. First Databank, Inc.* – in which First Databank, Inc., was found to have incorrectly stated the AWP of drugs compared to the actual market price for drugs. First Databank Inc., publishes pharmaceutical industry market information including drug pricing surveys of a drug wholesaler to determine benchmarks for what drug wholesalers charges drug retailers. Insurers and Medicaid programs use First Databank Inc.'s pricing information in order to establish reimbursement to pharmacies or other providers. The amendment after comments which relaxes the prior authorization requirement by granting approval from the moment that a pharmacist requested prior authorization is necessary given that sometimes prior authorization may take twenty-four (24) hours and pharmacists should not be penalized for the delay. The amendment after comments regarding claims is necessary to comply with a federal requirement and to motivate pharmacists to not wait more than a year to submit a claim for reimbursement.

- (c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statutes by replacing a drug pricing component that will no longer be published with one that will continue to be published. The drug pricing component is utilized to established Medicaid outpatient pharmacy program reimbursement. The amendment after comments which relaxes the prior authorization requirement by granting approval from the moment that a pharmacist requested prior authorization conforms to the content of authorizing statutes by not penalizing pharmacists for a delay in receiving prior authorization. The amendment after comments which requires a claim for a retroactively eligible individual to be submitted to DMS within 365 days of the individual's notification of becoming eligible conforms to the content of the authorizing statutes by ensuring claims are submitted per a federal requirement and by motivating providers to not wait more than a year to submit a claim.
- (d) How the amendment will assist in the effective administration of the statutes: The amendment will assist in the effective administration of the authorizing statutes by replacing a drug pricing component that will no longer be published with one that will continue to be published. The drug pricing component is utilized to established Medicaid outpatient pharmacy program reimbursement. The amendment after comments which relaxes the prior authorization requirement by granting approval from the moment that a pharmacist requested prior authorization will assist in the effective administration of the authorizing statutes by not penalizing pharmacists for a delay in receiving prior authorization. The amendment after comments which requires a claim for a retroactively eligible individual to be submitted to DMS within 365 days of the individual's notification of becoming eligible will assist in the effective administration of the authorizing statutes by ensuring claims are submitted per a federal requirement and by motivating providers to not wait more than a year to submit a claim.

- (3) List the type and number of individuals, businesses, organizations, or state and

local government affected by this administrative regulation: Pharmacies who dispense drugs to Medicaid recipients who are not enrolled with a managed care organization will be affected by this administrative regulation. Currently, there are over 1,100 pharmacies in Kentucky participating in the Medicaid program.

- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:
Pharmacies will not have to take any action regarding the original amendment. As a result of the amendment after comments, pharmacies will have to submit a claim for drugs dispensed to an individual who became retroactively eligible for Medicaid within 365 days of the individual being notified of retroactive eligibility. DMS will not reimburse for a claim submitted after 365 days from the notification.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). No cost is imposed.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Pharmacies will be reimbursed for dispensing drugs.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
 - (a) Initially: DMS estimates that changing the drug pricing component will be budget neutral.
 - (b) Ongoing: DMS estimates that changing the drug pricing component will be budget neutral.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and state matching funds of general fund appropriations.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding is necessary.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor directly nor indirectly increases any fee.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used) Tiering is applied in the sense that the dispensing fee for generic drugs is higher than the dispensing fee for brand name drugs in order to promote the dispensing of generic drugs.

FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation Number: 907 KAR 1:018

Agency Contact Person: Cindy Gray (502) 564-9444 or Stuart Owen (502) 564-4321

1. Federal statute or regulation constituting the federal mandate. 42 USC 1396a(a)(30), 42 CFR 447.204, and 42 USC 1396r-8.
2. State compliance standards. KRS 205.520(3) states, "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."
3. Minimum or uniform standards contained in the federal mandate. Medicaid reimbursement rates must be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the same geographic area.

Medicaid reimbursement for many covered outpatient drugs is subject to federal upper limits. A formula for calculating limits is established in federal law. Drug manufacturers must have an agreement to pay rebates to the state Medicaid program as a condition of receiving reimbursement. The rebate formula is also established in federal law. Both drug manufacturers and state Medicaid programs are required to report drug utilization and drug prices paid to the Centers for Medicare and Medicaid Services.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
The amendment does not impose stricter, additional or different requirements than those required by the federal mandate.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Stricter requirements are not imposed, a managed care model is not federally mandated for Medicaid programs.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation Number: 907 KAR 1:018

Agency Contact Person: Cindy Gray (502) 564-9444 or Stuart Owen (502) 564-4321

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments or school districts)?

Yes X No _____

If yes, complete 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) will be affected by this administrative regulation.
3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. This administrative regulation and 42 CFR 447.204 authorize the action taken by this administrative regulation.
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.
 - (c) How much will it cost to administer this program for the first year? DMS estimates that changing the drug pricing component will be budget neutral.
 - (d) How much will it cost to administer this program for subsequent years? DMS estimates that changing the drug pricing component will be budget neutral.