



FILED WITH LRC  
TIME: 8:30 AM  
JUN 01 2022  
Emily B Caudill  
REGULATIONS COMPILER

STATEMENT OF EMERGENCY  
907 KAR 23:020E

This emergency administrative regulation is being promulgated to establish and fully implement the single state managed care organization (MCO) pharmacy benefits manager (PBM) required by 2020's Senate Bill 50. This emergency administrative regulation is further being amended to implement critically needed 340B data tracking requirements. Implementing 340B data tracking requirements will allow the department to stay in compliance with SB 50 and assure that the department stays in compliance with the duplicate discount provision pursuant to 42 USC 256b(a)(5)(A)(i). In implementing SB 50, this emergency administrative regulation is being promulgated to clarify that a \$10.64 dispensing fee will be paid once per month per drug per pharmacy for all Medicaid outpatient prescriptions. In addition, this administrative regulation will allow for additional dispensing fees to be paid for compounded drugs and certain substance use disorder (SUD) drugs. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)3. to comply with the legislative mandate established in 2020's SB 50 to reorganize the outpatient pharmacy benefits managed by each contracted MCO's PBM to a single PBM for the entire managed care population. The single MCO PBM was procured and commenced operations on July 1, 2021. This emergency administrative regulation is also needed pursuant to KRS 13A.190(1)(a)2. to preserve state and federal funding. Failure to continue the single MCO PBM and comply with a received federal approval could result in a loss of federal funds. Finally, DMS needs this administrative regulation pursuant to KRS 13A.190(1)(a)1. to preserve the welfare of Medicaid recipients. Emergency implementation of this administrative regulation is necessary to ensure that the existing independent pharmacies remain viable and continue to reliably serve the Medicaid population in geographically diverse areas of the state.

This emergency administrative regulation shall be replaced by an ordinary administrative regulation. This emergency administrative regulation has the same number as an administrative regulation filed within the previous nine (9) months. This administrative regulation differs from the administrative regulation filed within the previous nine (9) months by including two new sections relating to 340B reimbursement. These amendments were necessary to comply with federal requirements relating to data submissions within the 340B program. The administrative regulation is also amended to allow certain substance use disorder (SUD) drugs to receive additional dispensing fees per month. This amendment was necessary following analysis that the applicable standard of care for certain SUD drugs justified multiple dispensing fees per month. The ordinary administrative regulation is identical to this emergency administrative regulation.

  
\_\_\_\_\_  
Andy Beshear  
Governor

  
\_\_\_\_\_  
Eric Friedlander, Secretary  
Cabinet for Health and Family Services

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Policy and Operations

4 (Emergency Administrative Regulation)

5 907 KAR 23:020E. Reimbursement for outpatient drugs.

6 RELATES TO: KRS 205.5510 to 205.5520, 205.560, 205.561, 205.5631, 205.5632,  
7 205.5634, 205.5636, 205.5638, 205.5639, 205.622, 205.6316(4), 217.015, 42 C.F.R. 440.120,  
8 447.45, 447.500 - 447.520, 42 U.S.C. 256b, 1396a - 1396d, 1396r-8

9 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.5514(1)(b),  
10 205.560, 205.561(2), 205.6316(4), 205.647(5), 42 U.S.C. 1396a(a)(30), 42 U.S.C. 1396r-8

11 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Ser-  
12 vices, Department for Medicaid Services has responsibility to administer the Medicaid Program.  
13 KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any re-  
14 quirement that may be imposed or opportunity presented by federal law to qualify for federal  
15 Medicaid funds. KRS 205.561(2) and 205.6316(4) require the department to promulgate an ad-  
16 ministrative regulation to establish the professional dispensing fee for covered drugs. This ad-  
17 ministrative regulation establishes the Medicaid Program reimbursement requirements, including  
18 the professional dispensing fee, for covered outpatient drugs dispensed to all enrolled Medicaid  
19 recipients [~~who are not enrolled with a managed care organization~~].

20 Section 1. Reimbursement. Reimbursement to a pharmacy or medical provider participating in  
21 the Medicaid Program for a covered outpatient drug provided to an eligible recipient shall be de-

1 terminated in accordance with the requirements established in this section. (1) A rebate agreement  
2 in accordance with 42 U.S.C. 1396r-8(a) shall be signed by the drug manufacturer, or the drug  
3 shall be provided based on an exemption from the rebate requirement established by 907 KAR  
4 23:010, Section 5(3).

5 (2) A pharmacy claim shall meet the point of sale (POS) requirements for services in accord-  
6 ance with 907 KAR 1:673.

7 (3) Reimbursement shall not be made for more than one (1) prescription to the same recipient  
8 during the same time period for a drug with the same:

9 (a) National Drug Code (NDC); or

10 (b) Drug or active ingredient name, strength, and dosage form.

11 (4) A timely claim payment shall be processed in accordance with 42 C.F.R. 447.45.

12 (a) In accordance with 42 C.F.R. 447.45, a claim shall be submitted to the department within  
13 twelve (12) months of the date of service.

14 (b) The department shall not reimburse for a claim submitted to the department after twelve  
15 (12) months from the date of service unless the claim is for a drug dispensed to an individual  
16 who was retroactively determined to be eligible for Medicaid.

17 (c) The department shall not reimburse a claim for a drug dispensed to an individual who was  
18 retroactively determined to be eligible for Medicaid after 365 days have lapsed from the date that  
19 the department issued the notice of retroactive eligibility.

20 (5) Reimbursement shall be denied if:

21 (a) The recipient is ineligible on the date of service;

22 (b) The drug is excluded from coverage in accordance with 907 KAR 23:010; or

23 (c) Prior authorization is required by the department and the request for prior authorization

1 has not been approved prior to dispensing the drug, except in an emergency supply situation.

2 (6) Pursuant to KRS 205.622, prior to billing the department, a provider shall submit a bill to  
3 a third party payer if the provider has knowledge that the third party payer may be liable for  
4 payment.

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

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

11 (7) There shall be no copayment or cost-sharing for an outpatient drug~~[Drug copayment re-~~  
12 ~~quirements and provisions shall be as established in 907 KAR 1:604].~~

13 (8) If a payment is made for a drug that was not administered or dispensed in accordance with  
14 907 KAR 23:010 or the payment was not appropriately reimbursed as required by this adminis-  
15 trative regulation, the provider shall refund the amount of the payment to the department or the  
16 department may, at its discretion, recoup the amount of the payment.

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

19 Section 2. Reimbursement Methodology. (1) Drug cost shall be determined in the pharmacy  
20 program using drug pricing and coding information obtained from nationally recognized com-  
21 prehensive drug data files with pricing based on the actual package size utilized.

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



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

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

5 (c) Federal upper limit or FUL, plus the professional dispensing fee, as established in Section  
6 3;

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

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

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

14 (4) Pursuant to KRS 205.5510 to 205.5520:

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

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

20 Section 3. Professional Dispensing Fee. (1) Effective April 1, 2017, the professional dispensing  
21 fee for a covered outpatient drug prescribed by an authorized prescriber and dispensed by a  
22 participating pharmacy provider in accordance with 907 KAR 23:010, and pursuant to a valid  
23 prescription shall be \$10.64 per pharmacy provider per recipient per drug per month.

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

3       (3)(a) As warranted by the applicable standard of care, the professional dispensing fee for a  
4 qualifying drug that is dispensed for the treatment of a substance use disorder shall be \$10.64 per  
5 pharmacy provider per recipient per drug reimbursed once every seven (7) days.

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

8       Section 4. Reimbursement Limitations. (1) Emergency supply. Dispensing of an emergency  
9 supply of a drug shall be made outside of the prescriber's normal business hours and as permitted  
10 in accordance with 907 KAR 23:010.

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

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

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

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

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

1 ingredient cost.

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

4 (6) ~~[340B Pharmacy Transactions.~~

5 ~~—(a) A pharmacy dispensing drugs purchased through the 340B Program pursuant to a 340B el-  
6 igible prescription from a covered entity shall bill the department no more than the actual 340B  
7 acquisition cost, plus the professional dispensing fee.~~

8 ~~—(b) For a 340B purchased drug dispensed by a pharmacy, the lowest of logic shall include the  
9 340B ceiling price.~~

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

13 ~~—(7) Physician administered drugs (PAD).~~

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

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

22 (c) 340B purchased PAD. For a drug purchased through the 340B Program and administered  
23 by a physician or the physician's authorized agent in an office or outpatient clinic setting, and

1 submitted for reimbursement as a medical benefit, the lowest of logic required by Section 2 of  
2 this administrative regulation shall include the 340B ceiling price. The covered entity shall bill  
3 no more than the actual 340B acquisition cost. A professional dispensing fee shall not be paid for  
4 PAD.

5 ~~[(8) Non-340B hemophilia products. Clotting factors acquired outside of the 340B Program~~  
6 ~~shall be reimbursed by the lowest of logic required by Section 2 of this administrative regulation,~~  
7 ~~which shall include the average sales price (ASP) plus six (6) percent. The professional dispens-~~  
8 ~~ing fee established by Section 3 of this administrative regulation shall also be paid.]~~

9 Section 5. 340B Pharmacy Transactions for Fee-For-Service. (1) A pharmacy dispensing  
10 drugs purchased through the 340B Program pursuant to a 340B eligible prescription from a cov-  
11 ered entity shall bill the department no more than the actual 340B acquisition cost, plus the pro-  
12 fessional dispensing fee.

13 (2) For a 340B purchased drug dispensed by a pharmacy, the lowest of logic shall include the  
14 340B ceiling price.

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

18 Section 6. 340B Pharmacy Transactions for Managed Care. (1) A pharmacy dispensing drugs  
19 purchased through the 340B Program pursuant to a 340B eligible prescription from a covered en-  
20 tity shall bill the department and be reimbursed pursuant to Section 2 of this administrative regu-  
21 lation.

22 (2) A 340B covered entity pharmacy shall notify the department on its own behalf and on be-  
23 half of any contracted pharmacy if it intends to use 340B drugs to fill prescriptions for qualified



1 pharmacy claims within the managed care Medicaid program.

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

5 1. A form shall be filed by the fifteenth (15<sup>th</sup>) of the last month of a quarter in order to be ef-  
6 fective for that quarter. A form that is submitted later than the fifteenth (15<sup>th</sup>) of the last month of  
7 a quarter shall be effective for the following quarter and until revoked.

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

9 (b) Any covered entity that no longer intends to participate and use 340B drugs to fill pre-  
10 scriptions for qualified pharmacy claims shall submit a complete and accurate "Kentucky Medi-  
11 caid 340B Nonparticipation Form".

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

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

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

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

19 Section 7. The maximum allowable cost, or MAC, shall be determined by taking into account  
20 each drug's cost, rebate status (non-rebateable or rebateable) in accordance with 42 U.S.C.  
21 1396r-8(a), marketplace status (obsolete, terminated, or regional availability), equivalency rating  
22 (A-rated), and relative comparable pricing. Other factors considered shall include clinical indica-  
23 tions of drug substitution, utilization, and availability in the marketplace. (1) Drug pricing re-

1 sources used to compare estimated acquisition costs for multiple-source drugs shall include com-  
2 prehensive data files maintained by a vendor under contract to the department, such as:

- 3 (a) NADAC as published by CMS;
- 4 (b) WAC, manufacturer's price list, or other nationally recognized sources;
- 5 (c) The Average Manufacturers Price for 5i Drugs as reported by CMS;
- 6 (d) ASP as published by CMS;
- 7 (e) Nationally recognized drug file vendors approved for use at a federal level and that have  
8 been approved by the department;
- 9 (f) Pharmacy providers; or
- 10 (g) Wholesalers.

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

13 (3) The process for a pharmacy provider to appeal a MAC price for a drug shall be as estab-  
14 lished in this subsection.

- 15 (a) The pharmacy provider shall email or fax a completed Kentucky Medicaid MAC Price  
16 Research Request Form to Kentucky's authorized agent in accordance with the instructions on  
17 the form.
- 18 (b) An appeal of a MAC price for a drug shall be investigated and resolved within three (3)  
19 business days.
- 20 (c) If available, the provider shall be supplied with the name of one (1) or more manufacturers  
21 who have a price comparable to the MAC price.
- 22 (d) The MAC price and effective date of that price shall be adjusted accordingly, retroactive  
23 to the date of service for the claim in question, if:

1 1. It is determined that a manufacturer does not exist in the price range referenced in para-  
2 graph (c) of this subsection; or

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

5 (e) If an adjusted MAC price becomes effective, the provider shall be informed that the claim  
6 may be rebilled for the price adjustment.

7 Section 7[6]. Federal Approval and Federal Financial Participation. The department's reim-  
8 bursement for services pursuant to this administrative regulation shall be contingent upon:

9 (1) Receipt of federal financial participation for the reimbursement; and

10 (2) Centers for Medicare and Medicaid Services' approval for the reimbursement.

11 Section 8[7]. Incorporation by Reference. (1) The following documents are incorporated by  
12 reference:

13 (a) "Kentucky Medicaid MAC Price Research Request Form", 2012; [~~is incorporated by ref-~~  
14 ~~erence~~].

15 (b) "Kentucky Medicaid 340B Participation Form", 2022.

16 (c) "Kentucky Medicaid 340B Nonparticipation Form", 2022.

17 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law,  
18 at:

19 (a) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky, Mon-  
20 day through Friday, 8:00 a.m. to 4:30 p.m.; or

21 (b) Online at the department's Web site at

22 <https://chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx> [~~[10](http://www.chfs.ky.gov/dms/incorp</a></del><br/>23 <del>erated.htm</del>].</p></div><div data-bbox=)~~

907 KAR 23:010

REVIEWED:

5/16/22  
Date

DocuSigned by:  
*Lisa Lee*  
7CB973024509415  
\_\_\_\_\_  
Lisa D. Lee, Commissioner  
Department for Medicaid Services

APPROVED:

5/20/2022  
Date

DocuSigned by:  
*Eric Friedlander*  
0AFA1D8C15D8421  
\_\_\_\_\_  
Eric Friedlander, Secretary  
Cabinet for Health and Family Services



**PUBLIC HEARING AND PUBLIC COMMENT PERIOD:**

A public hearing on this administrative regulation shall, if requested, be held on July 25, 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 July 18, 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 July 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.

**CONTACT PERSON:** Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-6746; Fax: 502-564-7091; CHFSregs@ky.gov.

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation Number: 907 KAR 23:010

Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov;  
and Krista Quarles, (502) 564-6746, CHFSRegs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the Department for Medicaid Services' (DMS's) reimbursement provisions and requirements regarding outpatient drugs dispensed or administered to all Medicaid recipients.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish DMS's reimbursement provisions and requirements regarding all outpatient drugs dispensed or administered to Medicaid recipients.

(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 DMS's reimbursement provisions and requirements regarding outpatient drugs dispensed or administered to all Medicaid recipients.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the authorizing statutes by establishing DMS's reimbursement provisions and requirements regarding outpatient drugs dispensed or administered to all Medicaid recipients.

(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: This amendment implements 2020's SB 50 and the department's awarded request for proposals as required by that legislation. The amendment further implements needed 340B data tracking measures in order to ensure that the Medicaid program is able to comply with federal law relating to duplicate discounts. 340B pharmacies are required to inform the department whether they will participate or not in providing 340B medications to Medicaid recipients. These changes are part of a new Section 5 and 6 of the administrative regulation that consolidate most 340B provisions. Section 5 is for Fee-For-Service 340B transactions and Section 6 is for MCO transactions. The administrative regulation is also amended to allow certain substance use disorder (SUD) drugs to receive additional dispensing fees per month by allowing the dispensing fee to be available once every seven days. The administrative regulation is amended to clarify when the professional dispensing fee can be assessed, clarify clotting factor reimbursement, and establish professional dispensing fees for compounded drugs. The regulation is further amended to remove cost-sharing and comply with 2021 Senate Bill 55's removal of all co-pays. In addition, the regulation is amended to clarify that both in-house and contract 340B pharmacy reimbursement do not include the 340B ceiling price in the lowest of logic methodology. In addition, clotting factor reimbursement is now addressed in Section 2 of the administrative regulation, as a result, Section 4(8) became redundant and is being deleted. Finally, additional citations have been included in the "Relates To" and "Statutory Authority" sections.

(b) The necessity of the amendment to this administrative regulation: This administrative regulation is needed to implement 2020's SB 50 and the department's awarded request for proposals as required by that legislation. In addition, 340B pharmacy claims are better tracked in order to comply with federal requirements.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment allows for the implementation of a single-state PBM as required by KRS 205.5512-.5520.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will allow for 2020's SB 50 to be fully implemented.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: All participating pharmacy providers dispensing covered drugs (approximately 1,500) and all participating medical providers administering covered drugs (approximately 46,000) will be affected by the administrative regulation.

(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: In order to be reimbursed by the DMS, participating providers will have to submit pharmacy or medical claims for covered outpatient drugs in accordance with this administrative regulation and applicable billing rules. In addition, 340B providers will need to submit participation or nonparticipation forms in order to inform DMS if they will be utilizing 340B drugs to fulfill Medicaid pharmacy claims.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs experienced by affected providers.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicable providers will benefit by receiving a true drug ingredient cost based reimbursement along with a professional dispensing fee from DMS for dispensing covered outpatient drugs to all Medicaid recipients.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

(b) On a continuing basis: DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Sources of funding to be used for the implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX and Title XXI of the Social Security Act, and state matching funds of general and agency 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: At this time,

---

**DMS does not assess that an increase in fees or funding is necessary to implement this administrative regulation.**

**(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.**

**(9) Tiering: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administration regulation applies equally to all those individuals or entities regulated by it.**



FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation Number: 907 KAR 23:020

Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov; and Krista Quarles, (502) 564-6746, CHFSRegs@ky.gov

1. 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? DMS will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560, 205.561(2), 205.6316(4), 42 U.S.C. 1396a(a)(30), 42 U.S.C. 1396r-8

3. 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? This administrative regulation is not expected to generate revenue for state or local government.

(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? This administrative regulation is not expected to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

(d) How much will it cost to administer this program for subsequent years? DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): \_\_\_\_\_

Expenditures (+/-): \_\_\_\_\_

Other Explanation: \_\_\_\_\_

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? DMS does not anticipate that cost savings will be generated for regulated entities as a result of the amendments to this administrative regulation in the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? DMS does not anticipate that cost savings will be generated for regulated entities as a result of the amendments to this administrative regulation in subsequent years.

(c) How much will it cost the regulated entities for the first year? DMS does not anticipate that regulated entities will incur costs as a result of this amendment in the first year.

(d) How much will it cost the regulated entities for subsequent years? DMS does not anticipate that regulated entities will incur costs as a result of this amendment in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings(+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]*

The administrative regulation will not have a major economic impact – as defined by KRS 13A.010 – on regulated entities. As drafted, DMS anticipates that this administrative regulation will provide equivalent or greater dispensing fee reimbursement for pharmacies than was available under the pharmacy reimbursement system prior to the passage of 2020's SB 50.

## FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation Number: 907 KAR 23:020

Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov;  
and Krista Quarles, (502) 564-6746, CHFSRegs@ky.gov

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. Part 447.
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. 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope as available to other individuals (non-Medicaid). Revising reimbursement methodology for outpatient drugs dispensed or administered to Medicaid recipients shall not change compliance standards.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? The administrative regulation does not impose stricter or different responsibilities than the federal requirements.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The administrative regulation does not impose stricter or different responsibilities than the federal requirements.

## SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

907 KAR 23:020E.

“Kentucky Medicaid 340B Participation Form”, 2022, this two (2) page document includes a letter explaining the need for the Participation Form, and describing certain legal requirements for 340B entities. The form includes areas for covered entity’s to submit information about themselves or their contracted pharmacy or third party administrator.

“Kentucky Medicaid 340B Nonparticipation Form”, 2022 this two (2) page document includes a letter describing the need for the Nonparticipation Form and the requirement that covered entities submit them. The form includes areas for covered entity’s to submit information about themselves or their contracted pharmacy or third party administrator.

The total number of pages incorporated by reference in this administrative regulation is four (4) pages.