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REGULATIONS COMPILER

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Policy and Operations

4 (Amended After Comments)

5 907 KAR 23:020. 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), 205.5514(1)(b), 205.520(3),
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 fee;
- 2 (b) Wholesale acquisition cost or WAC, plus the professional dispensing fee;
- 3 (c) Federal upper limit or FUL, plus the professional dispensing fee;
- 4 (d) Maximum allowable cost or MAC, plus the professional dispensing fee; or
- 5 (e) The provider's usual and customary charge to the public, as identified by the claim
- 6 charge[, plus the professional dispensing fee][price].

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

10 (4) Pursuant to KRS 205.5510 to 205.5520:

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

14 (b) The single PBM for the managed care population shall not discriminate against 340B con-
15 tract pharmacies via any reimbursement methodologies utilized. Section 3. Professional Dis-
16 pensing Fee. (1) Effective April 1, 2017, the professional dispensing fee for a covered outpatient
17 drug prescribed by an authorized prescriber and dispensed by a participating pharmacy provider
18 in accordance with 907 KAR 23:010, and pursuant to a valid prescription shall be \$10.64 per
19 pharmacy provider per recipient per drug per month.

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

22 Section 4. Reimbursement Limitations. (1) Emergency supply. Dispensing of an emergency
23 supply of a drug shall be made outside of the prescriber's normal business hours and as permitted

1 in accordance with 907 KAR 23:010.

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

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

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

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

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

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

18 (6) 340B Pharmacy Transactions.

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

22 (b) For a 340B purchased drug dispensed by a pharmacy, the lowest of logic shall include the
23 340B ceiling price.

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

4 (d) Reimbursement to a 340B in-house or contract pharmacy dispensing a 340B eligible pre-
5 scription for the managed care population shall not include the 340B ceiling price in the lowest
6 of logic.

7 (7) Physician administered drugs (PAD).

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

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

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

22 ~~[(8) Non-340B hemophilia products. Clotting factors acquired outside of the 340B Pro-~~
23 ~~gram shall be reimbursed by the lowest of logic required by Section 2 of this administrative~~

1 ~~regulation, which shall include the average sales price (ASP) plus six (6) percent. The pro-~~
2 ~~fessional dispensing fee established by Section 3 of this administrative regulation shall also~~
3 ~~be paid.]~~

4 Section 5. The maximum allowable cost, or MAC, shall be determined by taking into account
5 each drug's cost, rebate status (non-rebateable or rebateable) in accordance with 42 U.S.C.
6 1396r-8(a), marketplace status (obsolete, terminated, or regional availability), equivalency rating
7 (A-rated), and relative comparable pricing. Other factors considered shall include clinical indica-
8 tions of drug substitution, utilization, and availability in the marketplace. (1) Drug pricing re-
9 sources used to compare estimated acquisition costs for multiple-source drugs shall include com-
10 prehensive data files maintained by a vendor under contract to the department, such as:

- 11 (a) NADAC as published by CMS;
- 12 (b) WAC, manufacturer's price list, or other nationally recognized sources;
- 13 (c) The Average Manufacturers Price for 5i Drugs as reported by CMS;
- 14 (d) ASP as published by CMS;
- 15 (e) Nationally recognized drug file vendors approved for use at a federal level and that have
16 been approved by the department;
- 17 (f) Pharmacy providers; or
- 18 (g) Wholesalers.

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

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

23 (a) The pharmacy provider shall email or fax a completed Kentucky Medicaid MAC Price

1 Research Request Form to Kentucky's authorized agent in accordance with the instructions on
2 the form.

3 (b) An appeal of a MAC price for a drug shall be investigated and resolved within three (3)
4 business days.

5 (c) If available, the provider shall be supplied with the name of one (1) or more manufacturers
6 who have a price comparable to the MAC price.

7 (d) The MAC price and effective date of that price shall be adjusted accordingly, retroactive
8 to the date of service for the claim in question, if:

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

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

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

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

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

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

19 Section 7. Incorporation by Reference. (1) "Kentucky Medicaid MAC Price Research Request
20 Form", 2012, is incorporated by reference.

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

23 (a) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky, Mon-

- 1 day through Friday, 8:00 a.m. to 4:30 p.m.; or
- 2 (b) Online at the department's Web site at
- 3 <https://chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx> [<http://www.chfs.ky.gov/dms/incorp>
- 4 [rated.htm](#)].

907 KAR 23:010

REVIEWED:

11/5/2021

Date

DocuSigned by:

Lisa Lee

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Lisa D. Lee, Commissioner
Department for Medicaid Services

APPROVED:

11/5/2021

Date

DocuSigned by:

Eric Friedlander

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Eric Friedlander, Secretary
Cabinet for Health and Family Services

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 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. Finally, the regulation is amended to remove cost-sharing and comply with Senate Bill 55's removal of all co-pays.

The Amended After Comments version of the administrative regulation is amended to clarify that a professional dispensing fee is not needed when a usual and customary charge is paid for an outpatient pharmacy prescription. 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.

(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.

(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: _____

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.

STATEMENT OF CONSIDERATION RELATING TO
907 KAR 23:020

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Medicaid Services
Division of Policy and Operations

Amended After Comments

I. A public hearing on 907 KAR 23:020 was not requested or held. However, written comments were received during the public comment period.

II. The following individuals submitted comments during the public comment period:

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Chris Harlow, Pharm.D., Director of Pharmacy Services	Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy
Susan Sommer, CEO	Cordant Health Solutions
Rebecca Randall, Senior Director, Operations	WellCare Health Plans of Kentucky
Ben Mudd, Pharm.D., R.Ph, Executive Director	Kentucky Pharmacists Association
Rosemary Smith, R.Ph., Co-Founder	Kentucky Independent Pharmacist Alliance
Jonathan Scott, Regulatory and Legislative Advisor	Department for Medicaid Services, Commissioner's Office

III. The following individuals from the promulgating agency responded to comments received regarding 907 KAR 23:020.

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Lisa Lee, Commissioner	Department for Medicaid Services, Commissioner's Office
Veronica Cecil, Senior Deputy Commissioner	Department for Medicaid Services, Commissioner's Office
Fatima Ali, Interim Pharmacy Director	Department for Medicaid Services, Division of Policy and Operations

Alyssa Brainard, Pharmacy Intern	Department for Medicaid Services, Division of Policy and Operations
Jonathan Scott, Regulatory and Legislative Advisor	Department for Medicaid Services, Commissioner's Office

IV. SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Limitation of number of dispensing fees per month

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that the proposed requirement will cause pharmacy providers to lose reimbursement on prescriptions for which the applicable standard of medical care requires additional dispenses per month or during an applicable time period. A specific example of a 7-14 day interval for certain SUD MAT drugs is cited by the commenter. This commenter points out that Cordant Health Solutions has served more than 8,000 patients diagnosed with SUD and worked with over 160 MAT providers in the previous year.

(b) Response: DMS has evaluated the difference in dispensing fee both before and after the implementation of the single-state PBM and determined that there has not been a reduction in reimbursement. DMS furthermore believes that most providers are receiving increased reimbursement. The department will not be amending the administrative regulation in response to the comment.

(2) Subject: Amend administrative regulation to allow buprenorphine containing drugs to receive a dispensing fee each week that they are dispensed

(a) Comment: Ben Mudd, Executive Director, Kentucky Pharmacists Association, and Rosemary Smith, Co-Founder, Kentucky Independent Pharmacist Alliance, submitted comments discussing the current prescribing guidelines related to 201 KAR 9:270. These guidelines limit the prescribing of buprenorphine products to a maximum of 10 days during the month following induction of therapy and a maximum of 14 days during the second month of induction. "The majority of us in practice see prescribers continuing to limit their prescribing and therefor our dispensing to 7 to 14 days for an extended period based on the patient's progress. This creates a scenario where pharmacies are "often filling three of the four prescriptions filled each month without receiving a dispensing fee". KIPA contends that "the current reimbursement model is unsustainable for our members who fill a large number of buprenorphine products". The commenters request a new subsection that allows a \$10.64 dispensing fee each week for buprenorphine containing drugs used for medication assisted treatment.

(b) Response: The department's dispensing fees established pursuant to this administrative regulation should not impact the clinical methodology by which a clinician and a pharmacy meet their professional and statutory obligations in treating a patient's condition. In implementing this new single-PBM program, the department conducted a thorough analysis via a cost of dispensing survey. The department determined that the total dispensing fee received by a pharmacy, even in the case of multiple fills over twenty-three (23) days, is greater than the amount received prior to the implementation of the single-state PBM. In addition, a pharmacy would receive a drug cost

reimbursement for each fill during the twenty-three (23) day period. The department will not be amending the administrative regulation in response to the comment.

(3) Subject: Specialty pharmacy dispensing fee

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments highlighting the discussion at the October 2020 meeting of the Pharmacy Technical Advisory Committee (PTAC) and arguing that the dispensing fee of \$10.64 per pharmacy provider per recipient is inadequate to compensate specialty pharmacy providers. At this meeting a specialty pharmacy dispensing fee recommendation was proposed by the PTAC and was the mean specialty drug cost for dispensing as determined by the 2020 Cost-of-Dispensing Study. This suggested specialty pharmacy dispensing fee recommendation was \$73.58. A suggestion of a \$75-\$100 specialty pharmacy dispensing fee is made as well as a later request to utilize the \$73.58 dispensing fee.

(b) Response: The department has evaluated the recommendation to establish a higher specialty pharmacy dispensing fee, and has determined that it was unnecessary. The department will continue to evaluate specialty pharmacy costs and specialty pharmacy dispensing fees utilized in other states. However, no immediate higher dispensing fee will be implemented. The department will not be amending the administrative regulation in response to the comment.

(4) Subject: Reduction of 65% in drug ingredient reimbursement for generic buprenorphine/naloxone that has resulted in a 42% decline in overall buprenorphine reimbursement

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments pointing out an overall reduction in drug reimbursement that has occurred since the transition to a single-state PBM. The reduction is driven by a 65% reduction in drug reimbursement and has been mitigated by the dispensing fee increases. The net decrease is a 42% reduction in reimbursement for buprenorphine dispensing.

(b) Response: The reimbursement methodology currently utilized by the department is not substantially different than prior to July 1, 2021. The pharmacies continue to have all existing appeal options to request a reevaluation of a reimbursed cost. The department would encourage the pharmacies to exhaust all appeal options, as those are unchanged after the transition to the single-state PBM. The department will not be amending the administrative regulation in response to the comment, however, a thorough analysis of buprenorphine product ingredient costs will be performed. If a reprocessing of paid amounts is appropriate, this would follow the completed analysis.

(5) Subject: Vivitrol dispensing and administration expenses

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments indicating that the \$10.64 dispensing fee was inadequate to reimburse Cordant for Vivitrol dispensing and administration due to patient monitoring and management, medication use training, health care treatment assessments, and supply chain management functions including special storage, handling, and shipment services.

(b) Response: No change in reimbursement methodology has occurred as a result of this transition to a single-state PBM. The department has determined that this reimbursement and separate dispensing fee is appropriate for the costs of dispensing drugs. The department plans to continue evaluating the program at periodic intervals to consider additional dispensing fee needs. If additional health services are being provided within the pharmacy setting that are not otherwise reimbursable by the Medicaid program, it may be appropriate for the prescribing provider to pro-

vide additional reimbursement to the pharmacy when those services are provided. Currently, those services do not appear to be covered by the Medicaid program and would be appropriately addressed between clinician and pharmacist. The department will not be amending the administrative regulation in response to the comment.

(6) Subject: Sublocade care coordination

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments indicating that the \$10.64 dispensing fee was inadequate to reimburse Cordant for Sublocade dispensing and administration due to patient monitoring and management, medication use training, health care treatment assessments, and supply chain management functions including special storage, handling, and shipment services.

(b) Response: No change in reimbursement methodology has occurred as a result of this transition to a single-state PBM. The department has determined that this reimbursement and separate dispensing fee is appropriate for the costs of dispensing drugs. The department plans to continue evaluating the program at periodic intervals to consider additional dispensing fee needs. If additional health services are being provided within the pharmacy setting that are not otherwise reimbursable by the Medicaid program, it may be appropriate for the prescribing provider to provide additional reimbursement to the pharmacy when those services are provided. Currently, those services do not appear to be covered by the Medicaid program and would be appropriately addressed between clinician and pharmacist. The department will not be amending the administrative regulation in response to the comment.

(7) Subject: Specialty pharmacies and the applicable standard of care

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that specialty pharmacy providers are subject to the standard of care applied by the Kentucky Medical Board of Licensure to patients taking buprenorphine. This comment also discusses the practice of Kentucky prescribers in which they issue MAT prescriptions on a one-to-two week medication protocol for six (6) months or longer. The argument is that a specialty pharmacy would be subject to ongoing losses as a result of a once per every 23 days dispensing fee.

(b) Response: DMS has evaluated the difference in dispensing fee both before and after the implementation of the single-state PBM and determined that there has not been a reduction in reimbursement. DMS furthermore believes that most providers are receiving increased reimbursement. The department will not be amending the administrative regulation in response to the comment.

(8) Subject: Kentucky Opioid Response Effort (KORE) and DMS pharmacy

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments requesting that the DMS pharmacy regulation align with the goals established in the CHFS' KORE program goals

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments in an Appendix document suggesting that DMS is bound by the Commonwealth's KORE program goals.

(b) Response: The department appreciates the comment about aligning with the goals established in the CHFS KORE program, and will take these into consideration going forward. As a point of clarification, the department is not bound by that separate agency's recommendations about the opioid epidemic in determining reimbursement methodologies for pharmacy. The department will not be amending the administrative regulation in response to the comment.

(9) Subject: Express requirement of the PBM contract to be subject to DMS administrative regulations

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments requesting that the administrative regulation expressly state that the terms of the PBM contract are subject to "rules and regulations" promulgated by CHFS.

(b) Response: The terms of the PBM contract are subject to the administrative regulations promulgated by CHFS, specifically the Department for Medicaid Services. The department will not be amending the administrative regulation in response to the comment.

(10) Subject: Prohibition of reimbursement of a refill of a maintenance medication

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that the ordinary regulation's prohibition of reimbursement for a refill of a maintenance medication prior to the end of the dispensing period, unless this dispensing is in the best interest of the patient, reduces the Medicaid benefits of recipients in the Commonwealth. The commenter further argues that this requirement will cause pharmacy providers to lose reimbursement dollars when the standard of care requires refills of a maintenance medication. The commenter argues that the terms "maintenance medication" and "best interest of the recipient" should be defined, and that using a "best interest of the recipient" requirement allows for CHFS to make clinical and medical decision making that should instead be within the purview of the recipient's treating medical and pharmacy providers.

(b) Response: The department's dispensing fees established pursuant to this administrative regulation should not impact the clinical methodology by which a clinician and a pharmacy meet their professional and statutory obligations in treating a patient's condition. In implementing this new single-PBM program, the department conducted a thorough analysis via a cost of dispensing survey. The department determined that the total dispensing fee received by a pharmacy, even in the case of multiple fills over twenty-three (23) days, is greater than the amount received prior to the implementation of the single-state PBM. In addition, a pharmacy would receive a drug cost reimbursement for each fill during the twenty-three (23) day period. The department will not be amending the administrative regulation in response to the comment.

(11) Subject: Multiple case studies highlighting differences in reimbursement

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments showing patient case studies that highlight the differences in average reimbursement for several types of MAT drugs.

(b) Response: Kentucky Medicaid provides reimbursement for ingredient cost as well as a dispensing fee. The commenter has provided data that appears to combine both dispensing fee and ingredient cost reimbursement for these specific MAT drugs. DMS continues to estimate that average dispensing fee reimbursement has increased by more than \$8.00 for most pharmacy transactions. If the commenter is highlighting ingredient cost differences between the 2021 Spring, Summer, and Fall, it is important to stress that this administrative regulation does not modify the longstanding lowest of logic reimbursement system utilized within Kentucky Medicaid. The department encourages the commenter to use the preexisting process to appeal any ingredient cost reimbursement issues. The department will not be amending the administrative regulation in response to the comment, however, a thorough analysis of buprenorphine product ingredient costs

will be performed. If a reprocessing of paid amounts is appropriate, this would follow the completed analysis.

(12) Subject: Clotting Factor Reimbursement

(a) Comment: Rebecca Randall, Senior Director, Operations, WellCare Health Plans of Kentucky, submitted comments requesting that DMS clarify clotting factors when they are dispensed by a pharmacy or when it is administered in a physician's office. The request is that the administrative regulation be amended to specify that the Section 2(3) reimbursement only applies when a member obtains clotting factor from an outpatient pharmacy, and that if clotting factor is administered in a physician's office that the reimbursement shall be as established in Section 4(7) of the administrative regulation.

(b) Response: The administrative regulation correctly reflects the reimbursement based on whether or not the drug is obtained via a pharmacy or a physician's office. Clotting factor obtained from an outpatient pharmacy should be reimbursed pursuant to Section 2(3) of the administrative regulation. Clotting factor administered in a physician's office should be reimbursed pursuant to Section 4(7)(b). For clarification purposes, the department will amend the administrative regulation to remove Section 4(8).

(13) Subject: Inclusion of 340B in-house pharmacies within administrative regulation

(a) Comment: Jonathan Scott, Legislative and Regulatory Advisor, Department for Medicaid Services, submitted comments requesting that a clarification made to the emergency version of this administrative regulation – 907 KAR 23:020E- be included in this version of the administrative regulation as well. The emergency regulation was amended to acknowledge both in-house and contract pharmacies associated with a 340B Covered Entity.

(b) Response: After further consideration, the department will also include this provision in the ordinary administrative regulation. The department intends to continue clarifying this issue and promulgate a specific regulation relating to the 340B process. The department will amend the administrative regulation in response to the comment as follows:

Reimbursement to a 340B in-house or contract pharmacy dispensing a 340B eligible prescription for the managed care population shall not include the 340B ceiling price in the lowest of logic.

(14) Subject: Usual and Customary Charge

(a) Comment: Jonathan Scott, Legislative and Regulatory Advisor, Department for Medicaid Services, submitted comments indicating that the phrase "plus the professional dispensing fee" should not have been included when referring to a pharmacy's usual and customary charge. It is standard within this industry that no professional dispensing fee is charged in these cases. In addition, the department's federal financial approval does not include that a professional dispensing fee is available when a pharmacy requests reimbursement based on a usual and customary charge.

(b) Response: The department agrees with this comment and will delete the term from the regulation where it appears in conjunction with "usual and customary charge".

(15) Subject: Inclusion of additional citations

(a) Comment: Jonathan Scott, Legislative and Regulatory Advisor, Department for Medicaid Services, submitted comments highlighting four (4) additional citations to be added to the “Relates To” and “Statutory Authority” sections of the administrative regulation.

(b) The department agrees with these comments and will add the citations to the administrative regulation.

V. SUMMARY OF STATEMENT OF CONSIDERATION
AND
ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY

The Department for Medicaid Services (DMS) has considered the comments received regarding 907 KAR 23:020. This administrative regulation is being amended after comments. DMS is amending the administrative regulations as follows:

Relates To

Page 1

Line 7

After “205.5639,” insert “205.622.”

After “440.120,” insert “447.45.”

Statutory Authority

Page 1

Line 9

After “194A.050(1),” insert “205.5514(1)(b).”

Statutory Authority

Page 1

Line 10

After “205.6316(4),” insert “205.647(5).”

Section 2(2)(e)

Page 5

Line 6

Delete “plus the professional dispensing fee”.

Section 4(6)(d)

Page 7

Line 4

After “to a 340B” insert “in-house or”.

Section 4(8)

Page 7

Lines 20-23.

Delete lines 20-23 in their entirety.

(8) Non-340B hemophilia products. Clotting factors acquired outside of the 340B Program shall be reimbursed 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. The professional dispensing fee established by Section 3 of this administrative regulation shall also be paid.