

1 Public Protection Cabinet

2 Department of Insurance

3 Division of Health and Life Insurance and Managed Care

4 (Amendment)

5 806 KAR 17:575. Pharmacy benefit managers.

6 RELATES TO: KRS 304.1-050, 304.2-160, 304.2-165, 304.9-020, 304.17A-161,
7 304.17A-162

8 STATUTORY AUTHORITY: KRS 304.2-110, 304.2-160, 304.2-165, 304.9-020,
9 304.17A-161, 304.17A-162

10 NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes
11 ~~[provides that]~~ the commissioner to promulgate ~~[may make]~~ reasonable administrative
12 regulations necessary for, or as an aid to, the effectuation of any provision of the Kentucky
13 Insurance Code as defined in KRS 304.1-010. KRS 304.17A-162 requires the department to
14 promulgate an administrative regulation ~~[regulations]~~ to establish ~~[establishing]~~ the manner in
15 which a pharmacy benefit manager shall respond to an appeal regarding maximum allowable
16 cost pricing, the manner in which a pharmacy benefit manager shall make available the sources
17 for drug pricing data to contracted pharmacies ~~[makes available to contracted pharmacies~~
18 ~~information regarding sources for drug price data]~~, a comprehensive list of drugs subject to
19 maximum allowable cost and the actual maximum allowable cost for each drug, and weekly list

1 updates [~~updates to the list~~]. KRS 304.2-160, 304.2-165, 304.9-020, 304.17A-161, and 304.17A-
2 162 together authorize the department to promulgate an administrative [~~provide authority for the~~
3 ~~department's~~] regulation to establish the specific listing requirements and appeal processes
4 related to maximum allowable cost pricing for pharmacy benefit managers [~~of pharmacy benefit~~
5 ~~managers and the specific maximum allowable cost pricing and appeal process set forth in this~~
6 ~~administrative regulation~~]. This administrative regulation establishes [~~the process for a pharmacy~~
7 ~~benefit manager's maximum allowable cost appeals process,~~] the process for the department's
8 review of a complaint associated with a maximum allowable cost appeal[~~;~~] and the requirements
9 for the cost listings made available by a pharmacy benefit manager.

10 Section 1. Definitions. (1) "Contracted pharmacy" or "pharmacy" is defined by KRS
11 304.17A-161(1).

12 (2) "Department" is defined by KRS 304.1-050(2).

13 (3) "Maximum Allowable Cost" is defined by KRS 304.17A-161(3).

14 (4) "Pharmacy Benefit Manager" is defined by KRS 304.17A-161(4).

15 Section 2. Maximum Allowable Cost Pricing Appeal Process.

16 (1) A pharmacy benefit manager shall establish a maximum allowable cost pricing appeal
17 process where a contracted pharmacy or the pharmacy's designee may appeal if:

18 (a) The maximum allowable cost established for a drug reimbursement is below the cost
19 at which the drug is available for purchase by pharmacists and pharmacies in Kentucky from
20 national or regional wholesalers licensed in Kentucky by the Kentucky Board of Pharmacy; or

1 (b) The pharmacy benefit manager has placed a drug on the maximum allowable cost list
2 in violation of KRS 304.17A-162(8).

3 (2) The pharmacy benefit manager shall accept an appeal submitted by a contracted
4 pharmacy on or before sixty (60) days of the initial claim and the pharmacy benefit manager's
5 appeal process shall include the following:

6 [~~(a) The pharmacy benefit manager shall accept an appeal by a contracted pharmacy on~~
7 ~~or before sixty (60) days of the initial claim];~~

8 (a) [(b)] Notification to the appealing party that the appeal has been received, and the
9 names, addresses, email addresses, and telephone numbers of the pharmacy benefit manager's
10 contact persons for questions regarding the maximum allowable cost appeal process; and

11 (b) [(e)] A provision allowing a contracted pharmacy, pharmacy service administration
12 organization, or group purchasing organization, to initiate the appeal process, regardless if an
13 appeal has previously been submitted by a pharmacy or the pharmacy's designee outside of
14 Kentucky, by contacting the pharmacy benefit manager's designated contact person
15 electronically, by mail, or telephone. If the appeal process is initiated by telephone, the appealing
16 party shall follow up with a written request within three (3) days.

17 (3) The pharmacy benefit manager's maximum allowable cost pricing appeal process
18 shall be readily accessible to contracted pharmacies electronically, through publication on the
19 pharmacy benefit manager's website, and in either the contracted pharmacy's contract with the
20 pharmacy benefit manager or through a pharmacy provider manual distributed to contracted
21 pharmacies, pharmacy service administration organizations, and group purchasing organizations.

1 (4) For an appeal received from a pharmacy services administration organization or a
2 group purchasing organization related to a dispute regarding maximum allowable cost pricing, a
3 pharmacy benefit manager may request documentation that the pharmacy services administration
4 organization or group purchasing organization is acting on behalf of a contracted pharmacy
5 before responding to the appeal.

6 (5) The pharmacy benefit manager shall investigate, resolve, and respond to the appeal
7 within ten (10) calendar days of receipt of the appeal. Upon resolution, the pharmacy benefit
8 manager shall issue a written response to the appealing party that shall include the following:

9 (a) The date of the decision;

10 (b) The name, phone number, mailing address, email address, and title of the person
11 making the decision; and

12 (c) A statement setting forth the specific reason for the decision, including:

13 1. If the appeal is granted:

14 a. The amount of the adjustment to be paid retroactive to the initial date of service to the
15 appealing pharmacy;

16 b. The drug name, national drug code, and prescription number of the appealed drug; and

17 c. The appeal number assigned by the pharmacy benefit manager, if applicable; or

18 2. If the appeal is denied:

19 a. The national drug code of the appealed drug, or the national drug code of a
20 therapeutically equivalent drug as referenced [~~defined~~] in KRS 304.17A-162(9)₂ of the same
21 dosage, dosage form, and strength of the appealed drug; and

1 b. The Kentucky licensed wholesaler offering the drug at or below maximum allowable
2 cost on the date of fill.

3 (6) When a pharmacy benefit manager grants an appeal for which a price update is
4 warranted in accordance with KRS 304.17A-162(2), the pharmacy benefit manager shall
5 individually notify contracted pharmacies of the date of the granted appeal, the appealed drug,
6 initial date of service, national drug code, generic code number, applicable information to
7 identify the health benefit plan, and retroactive price update by the time of release of the next
8 scheduled maximum allowable cost update following the appeal decision by:

9 (a) Mail Courier;

10 (b) Electronic mail;

11 (c) Facsimile; or

12 (d) Web portal posting for sixty (60) days and corresponding electronic communication
13 to a contracted pharmacy with hyperlink to the portal for the granted appeal. A pharmacy benefit
14 manager shall include in the beginning and upon renewal of the contract with a pharmacy or the
15 pharmacy's representative, notice[5] and instructions for how to access and use the web portal.

16 (7) All contracted pharmacies permitted to reverse and resubmit claims following a
17 granted appeal pursuant to KRS 304.17A-162(2) shall submit claims to the pharmacy benefit
18 manager within sixty (60) days of notification that the appeal was granted.

19 (8) A pharmacy benefit manager shall submit the maximum allowable cost pricing appeal
20 process and a template response satisfying the requirements of subsection (5) of this section to
21 the department for review and approval.

1 Section 3. Department Review of Maximum Allowable Cost Pricing Appeal. (1) A
2 contracted pharmacy or the pharmacy’s designee may file a complaint with the department
3 following a final decision of the pharmacy benefit manager, ~~[to the department]~~ in accordance
4 with KRS 304.2-160 and 304.2-165.

5 (2) A complaint shall be submitted to the department no later than thirty (30) calendar
6 days from the date of the pharmacy benefit manager’s final decision.

7 (3) The department shall be entitled to request additional information necessary to resolve
8 a complaint from any party in accordance with KRS 304.2-165 and 304.17A-162(5).

9 Section 4. Maximum allowable cost list availability and format. (1) The pharmacy benefit
10 manager shall make available to the contracted pharmacy a comprehensive list of drugs subject
11 to maximum allowable cost pricing.

12 (2) The comprehensive maximum allowable cost pricing list shall:

13 (a) Be a complete listing by drug in an electronically accessible format ~~[, unless, upon a~~
14 ~~pharmacy’s written request the list be provided in a paper or other agreed format within two (2)~~
15 ~~business days upon receiving the necessary information required for each list requested;]~~

16 (b) Identify the applicable health plan for which the pricing is applicable;

17 (c) ~~[Be electronically searchable and sortable]~~ Contain the ability to search and sort drugs
18 electronically by individual drug name, national drug code, and generic code number;

19 (d) Contain data elements including the drug name, national drug code, per unit price,
20 and strength of drug;

1 (e) List a specific maximum allowable cost for each drug that will be reimbursed by the
2 pharmacy benefit manager;

3 (f) Provide the effective date for that maximum allowable cost price; and

4 (g) Provide the date the maximum allowable cost list was updated.

5 (3) The pharmacy benefit manager shall retain, in accordance with subsection (2)(a) of
6 this section, historical pricing data for a minimum of 120 days.

7 Section 5. Weekly Updates to Maximum Allowable Cost Price List.

8 (1) Pharmacy benefit managers shall send to all contracted pharmacies one (1) weekly
9 update to the maximum allowable cost price list.

10 (2) The weekly update shall include the information below for all drugs added, removed,
11 or changed in price since the last weekly update:

12 (a) Be in an electronically accessible format on the pharmacy benefit manager's website;
13 ~~unless, upon written request by the pharmacy the update be provided in paper or other agreed~~
14 ~~format within two (2) business days of receipt of the request from the contracted pharmacy];~~

15 (b) Identify the basis for each drug's inclusion on the update;

16 (c) If a drug is added to the maximum allowable cost list, the maximum allowable cost
17 price shall be indicated;

18 (d) Identify all drugs removed from the maximum allowable cost list;

19 (e) If a change in the maximum allowable cost price is made, include the old price, and
20 new price;

1 (f) Identify the drug name, national drug code, generic code number, and the applicable
2 health benefit plan information; and

3 (g) Identify the effective date of the change.

4 Section 6. Data Source Availability. Each pharmacy benefit manager shall identify
5 electronically or within contracts to all contracted pharmacies the national drug pricing
6 compendia, or sources used to obtain drug price data for those drugs, subject to maximum
7 allowable cost provisions. If any changes are made to the data sources following the execution of
8 a contract, the pharmacy benefit manager shall individually notify the contracted pharmacies of
9 the changes [~~either~~] through correspondence submitted electronically, by facsimile, or by mail
10 courier.

11 Section 7. Annual report. All pharmacy benefit managers licensed to do business in
12 Kentucky shall transmit [~~at least annually by March 31 to the department~~] a Pharmacy Benefit
13 Manager Annual Report to the department at least annually, by March 31 of each year.

14 Section 8. Incorporation by reference. (1) "Pharmacy Benefit Manager Annual Report,"
15 06, 2017 [~~June 2017~~], is incorporated by reference.

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17 law, at the Kentucky Department of Insurance, The Mayo-Underwood Building, 500 Mero Street
18 [~~215 West Main Street~~], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

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