

# Kentucky Department of Insurance

## Pharmacy Benefit Manager Review Guide

PBM ENTITY NAME \_\_\_\_\_ Incorporation/Formation Date \_\_\_\_\_

PBM Entity ID #: \_\_\_\_\_ Date of Receipt: \_\_\_\_\_ Check # or Online Payment Date \_\_\_\_\_

\_\_\_\_\_ Website Address \_\_\_\_\_

Address of Home Office: \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Business Address: \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Mailing Address: \_\_\_\_\_ P.O. Box \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Phone Number \_\_\_\_\_ Fax Number \_\_\_\_\_ Business E-Mail Address \_\_\_\_\_

Contact Person \_\_\_\_\_ Contact's Phone Number \_\_\_\_\_ Contact's E-mail address \_\_\_\_\_

Delegated Entitites	Delegated Functions

Administration & Operation	Compliant	Need Additional Information RE:	Policy Reference	REQUIREMENTS
<b>KRS 304.17A-162 (1) (a) PBM IDENTIFY SOURCES &amp; ESTABLISH APPEALS PROCESS RE: MAC PRICING</b>				
<p>Have a policy that PBM shall identify sources used to calculate drug reimbursement and establish a process to appeal and resolve disputes regarding maximum allowable cost pricing.</p> <p><a href="#">806 KAR 17:575</a> Process for MAC appeals process and process for the review of complaint associated with MAC appeal and requirements for the cost listings made available by a PBM.</p>				
<b>KRS 304.17A-162 (1) (b) APPEAL PROCESS &amp; 806 KAR 17:575</b>				
<p>Have a policy with detailed description of the MAC Pricing Dispute Appeal Process to be used by contracted pharmacies, pharmacy services and administration organizations of group purchasing organization, including the appeals policy and procedure, pursuant to <a href="#">KRS.17A-162 (1) (b)</a> and <a href="#">806 KAR 17:575</a>.</p>				
<p><a href="#">806 KAR 17:575 (2)</a> PBM shall establish a MAC pricing appeal process where a contracted pharmacy or the pharmacy's designee may appeal if</p> <p>(a) The maximum allowable cost established for a drug reimbursement is below the cost at which the drug is available for purchase by pharmacists and pharmacies in Kentucky from national or regional wholesalers licensed in Kentucky by the Kentucky Board of Pharmacy; or</p> <p>(b) The pharmacy benefit manager has placed a drug on the maximum allowable cost list in violation of <a href="#">KRS 304.17A-162(8)</a>.</p>				
<p>Right to appeal limited to 60 days following initial claim and PBM shall accept an appeal on or before 60 days of initial claim per <a href="#">806 KAR 17:575 (2) (a)</a></p>				
<p>Per <a href="#">806 KAR 17:575 (2)c)</a> A provision allowing a contracted pharmacy, pharmacy service administration organization or group purchasing organization, to initiate the appeal process, regardless if an appeal has previously been submitted by a pharmacy or the pharmacy's designee outside of Kentucky, by contacting the pharmacy benefit manager's designated contact person electronically, by mail, or telephone. If the appeal process is initiated by telephone, the appealing party shall follow up with a written request within three (3) days.</p>				
<p>Per <a href="#">806 KAR 17:575 (3)</a> The pharmacy benefit manager's maximum allowable cost pricing appeal process shall be readily accessible to contracted pharmacies electronically through publication on the pharmacy benefit manager's website, and in either the contracted pharmacy's contract with the pharmacy benefit manager or through a pharmacy provider manual distributed to contracted pharmacies, pharmacy service administration organizations, and group purchasing organizations.</p>				

<p><b>Acknowledgement Letter</b></p> <p>Per <a href="#">806 KAR 17:575 (5)</a> The pharmacy benefit manager shall investigate, resolve, and respond to the appeal within ten (10) calendar days of receipt of the appeal. Upon resolution, the pharmacy benefit manager shall issue a written response to the appealing party that shall include the following:</p> <p>(a) The date of the decision;</p> <p>(b) The name, phone number, mailing address, email address, and title of the person making the decision; and</p> <p>(c) A statement setting forth the specific reason for the decision, including specific requirements for appeals denied and granted. (Listed below)</p>			
<p>Detailed description of the MAC Pricing Dispute Appeal Process to be used by contracted pharmacies, pharmacy services and administration organizations of group purchasing organization, including the appeals policy and procedure, pursuant to <a href="#">KRS.17A-162 (1) (b)</a>.</p> <p>Appeals process should include following provisions:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Right to appeal limited to appeal received on or before 60 days following initial claim;</li> <li><input type="checkbox"/> The appeal shall be investigated and resolved by PBM within 10 calendar days;</li> <li><input type="checkbox"/> The PBM shall respond to all appeals in a manner approved by the department</li> </ul> <p><b>Denial Letter</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> If an appeal is denied the PBM shall provide the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> a.) the reason for the denial per <a href="#">KRS 17A-162</a> and additional requirements for <a href="#">806 KAR 17:575</a> including <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) The date of the decision;</li> <li><input type="checkbox"/> (b) The name, phone number, mailing address, email address, and title of the person making the decision; and</li> <li><input type="checkbox"/> (c) A statement setting forth the specific reason for the decision, including: <ul style="list-style-type: none"> <li>(i) The NDC or the NDC of a therapeutically equivalent drug as defined in <a href="#">KRS 304.17A-162(9)</a> of the same dosage, dosage form, and strength of the appealed drug and</li> <li>(ii) identify the source where (NDC) may be purchased from the Kentucky licensed wholesaler offering the drug at or below MAC on the date of fill the reason for the denial ((C)and where it may be purchased by contracted pharmacies)</li> </ul> </li> </ul> </li> </ul> </li> </ul>			
<b>KRS 304.17A-162 (2) (a-f) APPEALS GRANTED FOR PRICE UPDATES</b>			
<ul style="list-style-type: none"> <li><input type="checkbox"/> <a href="#">KRS 304/17A-162 (a)</a> and <a href="#">806 KAR 17:575 (5)(c)(1)</a> If the appeal is granted: Per <a href="#">806 KAR 17:575 (5)</a> The pharmacy benefit manager shall <b>investigate, resolve, and respond</b> to the appeal within ten (10) calendar days of receipt of the appeal. Upon resolution, the pharmacy benefit manager shall issue a written response to the appealing party that shall include the following: <ul style="list-style-type: none"> <li>(a) The date of the decision;</li> </ul> </li> <li><input type="checkbox"/> (b) The name, phone number, mailing address, email address, and title of the person making the decision; and</li> <li><input type="checkbox"/> (c) A statement setting forth the specific reason for the decision, including: <a href="#">KRS 304/17A-162 (a)</a> and <a href="#">806 KAR 17:575 (5)(c)(1)</a> If the appeal is granted:</li> </ul>			

<ul style="list-style-type: none"> <li><input type="checkbox"/> (i) The amount of the adjustment to be paid retroactive to the initial date of service to the appealing pharmacy, (which is the date appealed drug was dispensed);</li> <li>(ii) The drug name, national drug code, and prescription number of the appealed drug;</li> <li>(iii) The appeal number assigned by the pharmacy benefit manager, if applicable</li> </ul> <p>PLUS <a href="#">(a-f of statute 162)</a> items listed below.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> If a price update is warranted as a result of an appeal granted the PBM shall: <ul style="list-style-type: none"> <li><input type="checkbox"/> A.) make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed;</li> <li><input type="checkbox"/> B.) adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that PBM that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed;</li> <li><input type="checkbox"/> C.) individually notify all other contracted pharmacies in the network of that PBM that a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed;</li> <li><input type="checkbox"/> D.) adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost if applicable to their contract;</li> <li><input type="checkbox"/> E.) allow the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed; and</li> <li><input type="checkbox"/> F.) make retroactive price adjustments in the next payment cycle.</li> </ul> </li> </ul>			
<p><a href="#">806 KAR 17:575 (8)</a> A pharmacy benefit manager shall submit the maximum allowable cost pricing appeal process and a template response satisfying the requirements of subsection (5) of this section to the department for review and approval. <a href="#">806 KAR 17:575(8)</a></p>			
<b>KRS 304.17A-162 (3) NATIONAL DRUG SOURCES USED TO ESTABLISH MAC FOR REIMBURSEMENT</b>			
<p>Identify the national drug pricing compendia or sources used to obtain drug price data (in a manner established by administrative regulations promulgated by the department) for every drug for which the PBM establishes a maximum allowable cost to determine the drug product reimbursement. Section 6. Data Source Availability. Each pharmacy benefit manager shall identify electronically or within contracts to all contracted pharmacies the national drug pricing compendia or sources used to obtain drug price data for those drugs subject to maximum allowable cost provisions. If any changes are made to the data sources following the execution of a contract, the pharmacy benefit manager shall individually notify the contracted pharmacies of the changes either through correspondence submitted electronically, facsimile, or mail courier. <a href="#">KRS 304.17A-162(3)</a></p>			
<b>KRS 304.17A-162 (4) EACH DRUG SUBJECT TO MAC &amp; ACTUAL MAC</b>			
<p>Identify the location of the PBM's comprehensive list of every drug subject to MAC for each drug and the actual maximum allowable cost for each drug.</p>			

<p>Make available the PBM's comprehensive list of every drug subject to MAC for each drug and the actual maximum allowable cost for each drug.</p> <p>Section 4. Maximum allowable cost list availability and format. (1) The pharmacy benefit manager shall make available to the contracted pharmacy a comprehensive list of drugs subject to maximum allowable cost pricing.</p> <p>(2) The comprehensive maximum allowable cost pricing list shall:</p> <p>(a) Be a complete listing by drug in an electronically accessible format, unless, upon a pharmacy's written request the list be provided in a paper or other agreed format within two (2) business days upon receiving the necessary information required for each list requested;</p> <p>(b) Identify the applicable health plan for which the pricing is applicable;</p> <p>(c) <b>Be electronically searchable and sortable by individual drug name, national drug code, and-generic code number;</b></p> <p>(d) <b>Contain data elements including the drug name, national drug code, per unit price, and strength of drug;</b></p> <p>(e) List a specific maximum allowable cost for each drug that will be reimbursed by the pharmacy benefit manager;</p> <p>(f) Provide the effective date for that maximum allowable cost price; and</p> <p>(g) Provide the date the maximum allowable cost list was updated.</p> <p>(3) The pharmacy benefit manager shall retain in accordance with subsection (2)(a) of this section historical pricing data for a minimum of 120 days. <a href="#">KRS 304.17A-162(4)</a></p>			
<b>KRS 304.17A-162 (5) &amp; 304.2-165 REQUESTED INFO TO RESOLVE APPEAL PROVIDED TO DEPARTMENT</b>			
<p>Have a policy that upon request, information that is needed to resolve an appeal shall be made available to the department within 15 calendar days and if the department is unable to obtain information from the PBM appeal shall be granted to the appealing pharmacy. <a href="#">KRS 304.17A-162(5)</a> &amp; <a href="#">304.2-165</a></p>			
<b>KRS 304.17A-162 (6) UPDATE MAC PRICING EVERY 7 DAYS &amp; NOTIFY CONTRACTED PHARMACIES</b>			
<p>Have a policy and procedure used for updating MAC pricing (for every drug PBM establishes MAC to determine reimbursement) every 7 calendar days and shall immediately utilize the updated MAC in calculating the payments made to all contracted pharmacies (and the PBM's ability to provide notification to all contractors. <i><b>This update must be every 7 calendar days from the change in pricing, not a once weekly update.</b></i> <a href="#">KRS 304.17A-162(6)</a></p>			
<b>KRS 304.17A-162 (7) &amp; 806 KAR 17:575 WEEKLY UPDATES TO MAC &amp; ACTUAL COST NOTIFICATIONS</b>			
<p>Have a policy and procedure indicating PBMs ability to provide notification to all contracted pharmacies to the pharmacists the weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.</p> <p>Section 5. Weekly Updates to Maximum Allowable Cost Price List.</p> <p>(1) Pharmacy benefit managers shall send to all contracted pharmacies one (1) weekly update to the maximum allowable cost price list.</p> <p>(2) The weekly update shall include the information below for <b>all drugs added, removed, or changed in price since the last weekly update:</b></p>			

<p>(a) Be in an electronically accessible format, unless, upon written request by the pharmacy the update be provided in paper or other agreed format within two (2) business days of receipt of the request from the contracted pharmacy;</p> <p>(b) Identify the basis for each drug’s inclusion on the update;</p> <p>(c) If a drug is added to the maximum allowable cost list, the maximum allowable cost price shall be indicated;</p> <p>(d) Identify all drugs removed from the maximum allowable cost list;</p> <p>(e) If a change in the maximum allowable cost price is made, <b>include the old price, and new price;</b></p> <p>(f) <b>Identify the drug name, national drug code, generic code number, and the applicable health benefit plan information;</b> and</p> <p>(g) Identify the effective date of the change.</p> <p><a href="#">KRS 304.17A-162(7)</a> &amp; <a href="#">806 KAR 17:575</a></p>			
<b>KRS 304.17A-162 (8) DRUG PRODUCTS &amp; TEEs SUBJECT TO MAC ARE AVAILABLE</b>			
<p>Ensure every drug subject to PBM’s maximum allowable costs are:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> A.) Generally available for purchase by pharmacists and pharmacies in Kentucky from a national or regional wholesaler licensed in Kentucky by the Kentucky Board of Pharmacy;</li> <li><input type="checkbox"/> B.) Not obsolete, temporarily unavailable, or listed on a drug shortage list; and</li> <li><input type="checkbox"/> C1.) Drugs that have an “A” or “B” rating in the most recent version of the United States Food and Drug Administration Approved (USDA) Drug Products with Therapeutic Equivalence Evaluations(TEE), also known as the Orange Book; or</li> <li><input type="checkbox"/> C2.) Drugs that have a “NR” or “NA” rating or have a similar rating by a nationally recognized reference. <a href="#">KRS 304.17A-162(8)</a></li> </ul>			
<b>KRS 304.17A-162 (9) REIMBURSEMENTS ARE FOR SPECIFIC DRUG PRODUCTS &amp; TEEs</b>			
<p>Have a policy to ensure that reimbursement for a drug subject to maximum allowable cost is based solely on specific drug and drugs that are therapeutically equivalent if the therapeutically equivalent drugs are listed in the most recent version of the Orange Book (which is USDA Approved Drug Products with Therapeutic Equivalence Evaluations). <a href="#">KRS 304.17A-162(9)</a></p>			
<b>KRS 304.17A-162 (10) REIMBURSEMENT FOR “B” DRUG PRODUCTS &amp; TEEs</b>			
<p>Have a policy to ensure that reimbursement for a “B” rated drug subject to maximum allowable cost is based solely on specific drug and drugs that are not therapeutically equivalent to a “B” rating in the most recent version of the Orange Book. <a href="#">KRS 304.17A-162(10)</a></p>			
<b>KRS 304.17A-162 (11) REIMBURSEMENT FOR “NR” OR “NA” DRUG PRODUCTS &amp; TEEs</b>			
<p>Have a policy to ensure that reimbursement for a “NR” or “NA” rating or similar rating by a nationally recognized reference subject to maximum allowable cost is based solely on that specific drug and other drugs with a “NR” or “NA” rating or similar rating by a nationally recognized reference that meets criteria for therapeutic equivalence used in the Orange Book. <a href="#">KRS 304.17A-162(11)</a></p>			
<b>KRS 304.17A-162 (12) REIMBURSEMENT FOR DRUG PRODUCT WITHOUT TEE</b>			
<p>Have a policy to ensure that reimbursement for a drug subject to maximum allowable cost is based solely on that drug if there is no other therapeutically equivalent drug. <a href="#">KRS 304.17A-162(12)</a></p>			
<b>KRS 304.17A-162 (13) REIMBURSEMENT FOR DRUG PRODUCTS ARE AVAILABLE</b>			

Have a policy to ensure that reimbursement for a drug subject to maximum allowable cost is not based on a drug that is obsolete, temporarily unavailable, listed on a drug shortage list, or that cannot be lawfully substituted. <a href="#">KRS 304.17A-162(13)</a>			
<b>KRS 304.17A-167 STANDARDS FOR ELECTRONIC PRIOR AUTHORIZATIONS</b>			
Have a process for electronically requesting and transmitting prior authorization for a drug by providers that meets the requirement of the most recent National Council for Prescription Drug Programs SCRIPT standards for electronic prior authorization transactions adopted by the US Dept. of Health and Human Services. <a href="#">KRS 304.17A-167</a>			
<b>45 CFR 156.122 EXCEPTIONS POLICY &amp; POLICY TO ACCESS RETAIL PHARMACY</b>			
Have an <i>Exceptions Policy</i> which allows an enrollee, designee, or prescribing provider to gain access to clinically appropriate drugs not otherwise covered by the plan within 72 hours, and includes a <b>standard</b> procedure. <a href="#">45 CFR 156.122</a>			
Have an <i>Exceptions Policy</i> which allows an enrollee, designee, or prescribing provider to gain access to clinically appropriate drugs not otherwise covered by the plan which includes an <b>expedited</b> procedure.			
Have a policy that explains the process that gives the ability to access prescriptions from an in-network retail, unless special handling or another reason proves that the prescription cannot be provided by a retail pharmacy.			
<b>OTHER POLICIES POLICY RE: PHARMACY &amp; THERAPEUTICS COMMITTEE</b>			
Have a policy and procedure relating to the resolution of MAC pricing complaints which are filed with the Kentucky Department of Insurance, including timeframes and sample appeal response letter. Include a sample of following letters/templates: a.) acknowledgement letter b.) appeal granted from PBM to pharmacist c.) appeal denial from PBM to pharmacist d.) individual notification informing all contracted pharmacies of an adjustment in reimbursement as a result of a granted appeal.			
Have a policy explaining any Pharmacy and Therapeutics committee membership standards and duties, including how often the committee meets, structure, and the decision-making process.			
<a href="#">Section 7 of KAR 17:575</a> : Annual report. All pharmacy benefit managers licensed to do business in Kentucky shall transmit at least annually by March 31 to the department a Pharmacy Benefit Manager Annual Report. Please find the Annual Report <a href="#">here</a> . <b>Or, it can be submitted electronically if you have an eServices account.</b>			
<b>All supporting documentation including but not limited to <a href="#">Provider Agreement</a> templates if any responsibilities are delegated and <a href="#">Pharmacy Agreement</a> templates. <b>Please note that any delegated entities must be Kentucky Licensed prior to the approval of your submitted renewal.</b></b>			
<b>OTHER REQUIREMENTS MAY BE VERIFIED BY LICENSURE</b>			
Have proof of financial responsibility in the amount of one million dollars (\$1,000,000).			

Have proof of registration with the Kentucky Secretary of State’s office in order to do business in Kentucky.			
Have \$1,000 non-refundable fee ( <a href="#">KRS 304.9-200(4)</a> ), made payable to the Kentucky State Treasurer. The fee may also be paid through <a href="#">eServices</a> . To pay application fees through eServices, a “ <b>Business Entity – License Administrator</b> ” account is required. Allow 48 hours after receipt of application to pay these fees under “pay pending fees” from the menu.			

## FOR DEPARTMENT USE ONLY

<b>PBM Coordinator Received:</b>		
<b>PBM Coordinator Initial Review Completed:</b>		
<b>Suspense/Objection Letter Sent:</b>		
<b>Response Received from PBM:</b>		
<b>Completion of PBM Health Requirements:</b>	<hr style="width: 50%; margin: 0 auto;"/> Date of Health Review Completed	<hr style="width: 50%; margin: 0 auto;"/> Reviewer signature