

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

Please add companies that delegate to your entity or that you delegate to in the above box and specify if your company delegates or is contracted.

Administration & Operation	Compliant	Need Additional Information RE:	Policy Reference
KRS 304.17A-162 (1) (a) PBM IDENTIFY SOURCES & ESTABLISH APPEALS PROCESS RE: MAC PRICING			
<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>806 KAR 17:575 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>			
KRS 304.17A-162 (1) (b) APPEAL PROCESS & 806 KAR 17:575			
<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 KRS.17A-162 (1) (b) and 806 KAR 17:575. PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</p>			
<p>806 KAR 17:575 (2) 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 KRS 304.17A-162(8). PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</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 806 KAR 17:575 (2) (a) and 304.17A-162 (1)(b)(1)</p>			
<p>Per 806 KAR 17:575 (3)b 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. PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</p>			
<p>Per 806 KAR 17:575 (4) and KRS 304.17A-162 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>			

REQUIREMENTS

<p>Acknowledgement Letter</p> <p>Per 806 KAR 17:575 (6), 806 KAR 17:575 (2)(6), 806 KAR 17:575 (2)(7) and 304.17A-162 (1)(b)(2) 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> <ul style="list-style-type: none"> (a) The date of the decision; (b) The name, phone number, mailing address, email address, and title of the person making the decision; and (c) A statement setting forth the specific reason for the decision, including specific requirements for appeals denied and granted. (Listed below) PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM. 			
<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 KRS.17A-162 (1) (b).</p> <p>Appeals process should include following provisions:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Right to appeal limited to appeal received on or before 60 days following initial claim; <input type="checkbox"/> The appeal shall be investigated and resolved by PBM within 10 calendar days; <input type="checkbox"/> The PBM shall respond to all appeals in a manner approved by the department <ul style="list-style-type: none"> <input type="checkbox"/> 806 KAR 17:575(2)(9) A pharmacy benefit manager shall submit the maximum allowable cost pricing appeal process and a template response satisfying the requirements of 806 KAR 17:575(2)(5) to the department for review and approval. 806 KAR 17:575(8) and 304.17A-162 (1)(b)(3) <p>Denial Letter</p> <ul style="list-style-type: none"> <input type="checkbox"/> If an appeal is denied the PBM shall provide the following: <ul style="list-style-type: none"> <input type="checkbox"/> a.) the reason for the denial per KRS 17A-162 and additional requirements for 806 KAR 17:575 including <ul style="list-style-type: none"> (a) The date of the decision; (b) The name, phone number, mailing address, email address, and title of the person making the decision; and (c) A statement setting forth the specific reason for the decision, including: <ul style="list-style-type: none"> (i) The NDC or the NDC of a therapeutically equivalent drug as defined in KRS 304.17A-162(9) of the same dosage, dosage form, and strength of the appealed drug and (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)806 KAR 17:575(2)(9) <input type="checkbox"/> A pharmacy benefit manager shall submit the maximum allowable cost pricing appeal process and a template response satisfying the requirements of 806 KAR 17:575(2)(5) to the department for review and approval. 806 KAR 17:575(8) and 304.17A-162 (1)(b)(3) 			

KRS 304.17A-162 (2) (a-f) APPEALS GRANTED FOR PRICE UPDATES

<ul style="list-style-type: none"> <input type="checkbox"/> KRS 304.17A-162 (2)(a) and 806 KAR 17:575 (6)(c)(1) If the appeal is granted: Per 806 KAR 17:575(2)(6)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: <ul style="list-style-type: none"> (a) The date of the decision; <input type="checkbox"/> (b) The name, phone number, mailing address, email address, and title of the person making the decision; and <input type="checkbox"/> (c) A statement setting forth the specific reason for the decision, including: KRS 304.17A-162 (2)(a-f) and 806 KAR 17:575 (2)(6)(c)(1) If the appeal is granted: <ul style="list-style-type: none"> <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); <input type="checkbox"/> (ii) The drug name, national drug code, and prescription number of the appealed drug; <input type="checkbox"/> (iii) The appeal number assigned by the pharmacy benefit manager, if applicable <input type="checkbox"/> PLUS (a-f of statute 162) items listed below. <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"> <input type="checkbox"/> A.) make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed; <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; <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; <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; <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 <input type="checkbox"/> F.) make retroactive price adjustments in the next payment cycle. 			
<p>806 KAR 17:575(2)(9) A pharmacy benefit manager shall submit the maximum allowable cost pricing appeal process and a template response satisfying the requirements of 806 KAR 17:575(2)(5) to the department for review and approval. 806 KAR 17:575(8) and 304.17A-162 (1)(b)(3)</p>			

KRS 304.17A-162 (3) NATIONAL DRUG SOURCES USED TO ESTABLISH MAC FOR REIMBURSEMENT			
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. KRS 304.17A-162(3)			
KRS 304.17A-162 (3) & KRS 304.17A-162 (4) EACH DRUG SUBJECT TO MAC & ACTUAL MAC			
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. KRS 304.17A-162(4)			
<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 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) Be electronically searchable and sortable by individual drug name, national drug code, and-generic code number;</p> <p>(d) Contain data elements including the drug name, national drug code, per unit price, and strength of drug;</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. 806 KAR 17:575 (4)(2)</p>			
KRS 304.17A-162 (5) & 304.2-165 REQUESTED INFO TO RESOLVE APPEAL PROVIDED TO DEPARTMENT			
Have a policy that upon request, information that is needed to resolve an appeal shall be made available to the Kentucky Department of Insurance within 15 calendar days and if the department is unable to obtain information from the PBM appeal shall be granted to the appealing pharmacy. KRS 304.17A-162(5) & 304.2-165			

KRS 304.17A-162 (6) UPDATE MAC PRICING EVERY 7 DAYS & NOTIFY CONTRACTED PHARMACIES

<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>This update must be every 7 calendar days from the change in pricing, not a once weekly update.</i> KRS 304.17A-162(6) PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</p>			
KRS 304.17A-162 & 806 KAR 17:575 WEEKLY UPDATES TO MAC & ACTUAL COST NOTIFICATIONS			
<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. Section 5. Weekly Updates to Maximum Allowable Cost Price List. (1) Pharmacy benefit managers shall send to all contracted pharmacies one (1) weekly update to the maximum allowable cost price list. (2) The weekly update shall include the information below for all drugs added, removed, or changed in price since the last weekly update: (a) Be in an electronically accessible format, unless, upon written request by the pharmacy the update be provided in paper or other agreed format upon receipt of the request from the contracted pharmacy; (b) Identify the basis for each drug’s inclusion on the update; (c) If a drug is added to the maximum allowable cost list, the maximum allowable cost price shall be indicated; (d) Identify all drugs removed from the maximum allowable cost list; (e) If a change in the maximum allowable cost price is made, include the old price, and new price; (f) Identify the drug name, national drug code, generic code number, and the applicable health benefit plan information; and (g) Identify the effective date of the change. KRS 304.17A-162(7) & 806 KAR 17:575 (5)(2) PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</p>			
KRS 304.17A-162 DRUG PRODUCTS & TEEs SUBJECT TO MAC ARE AVAILABLE			
<p>Ensure every drug subject to PBM’s maximum allowable costs are:</p> <ul style="list-style-type: none"> <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; <input type="checkbox"/> B.) Not obsolete, temporarily unavailable, or listed on a drug shortage list; and <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 KRS 304.17A-162(10); or <input type="checkbox"/> C2.) Drugs that have a “NR” or “NA” rating or have a similar rating by a nationally recognized reference. KRS 304.17A-162(11) <p>Any methodologies utilized, or to be utilized, by the pharmacy benefit manager in connection with reimbursement, which shall:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Comply with SB188 (3)(2)(c); and <input type="checkbox"/> Be used in determining all appeals under KRS 304.17A-162 <p>PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</p>			

KRS 304.17A-162 (9) REIMBURSEMENTS ARE FOR SPECIFIC DRUG PRODUCTS & TEEs			
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). KRS 304.17A-162(9) PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.			
KRS 304.17A-162 (10) REIMBURSEMENT FOR "B" DRUG PRODUCTS & TEEs			
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. KRS 304.17A-162(10)			
KRS 304.17A-162 (11) REIMBURSEMENT FOR "NR" OR "NA" DRUG PRODUCTS & TEEs			
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. KRS 304.17A-162(11)			
KRS 304.17A-162 (12) REIMBURSEMENT FOR DRUG PRODUCT WITHOUT TEE			
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. KRS 304.17A-162(12)			
KRS 304.17A-162 (13) REIMBURSEMENT FOR DRUG PRODUCTS ARE AVAILABLE			
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. KRS 304.17A-162(13)			
KRS 304.17A-167 STANDARDS FOR ELECTRONIC PRIOR AUTHORIZATIONS			
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. KRS 304.17A-167			

45 CFR 156.122 EXCEPTIONS POLICY & POLICY TO ACCESS RETAIL PHARMACY

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 standard procedure. 45 CFR 156.122 (c)(1)(ii) PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.			
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 expedited (24hrs) procedure. 45 CFR 156.122 (c)(2)(iii)			
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. 45 CFR 156.122 (e)(1) *A new section will be added to KRS 304.17A for 2025			

OTHER POLICIES POLICY RE: PHARMACY & THERAPEUTICS COMMITTEE			
<p>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.</p> <p>Include a sample of following letters/templates:</p> <p>a.) acknowledgement letter</p> <p>b.) appeal granted from PBM to pharmacist</p> <p>c.) appeal denial from PBM to pharmacist</p> <p>d.) individual notification informing all contracted pharmacies of an adjustment in reimbursement as a result of a granted appeal.</p> <p>PLEASE NOTE: IF THIS IS DELEGATED, PLEASE SPECIFY SPECIFICALLY WHAT FUNCTION IS DELEGATED AND TO WHOM.</p>			
<p>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. PLEASE NOTE: P&T COMMITTEE POLICIES MUST BE PROVIDED. IF THIS IS DELEGATED TO ANOTHER ENTITY, PLEASE SPECIFY WHAT COMPANY.</p> <p>45 CFR 156.122 (a) & 806 KAR 9:360 (2)(f)(3)</p>			
<p>Section 7 of KAR 17:575: 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 here. <u>Or, it can be submitted electronically if you have an eServices account.</u></p>			
<p>All supporting documentation including but not limited to Provider Agreement templates if any responsibilities are delegated and Pharmacy Agreement templates. <u>Please note that any delegated entities must be Kentucky Licensed prior to the approval of your submitted renewal.</u></p>			
OTHER REQUIREMENTS MAY BE VERIFIED BY LICENSURE			
<p>Have proof of financial responsibility in the amount of one million dollars (\$1,000,000).</p>			
<p>Have proof of registration with the Kentucky Secretary of State's office in order to do business in Kentucky.</p>			
<p>Have \$1,000 non-refundable fee paid through the PBM's Kentucky eServices account. Renewal fees may be paid by selecting "License Renewal Invoice" from the eServices menu.</p> <p>For a new, initial PBM license application, fees may be paid through eServices by selecting "Pay Pending Fees" from the menu 48 hours after DOI has received the application.</p> <p>For help with eServices, please contact the Licensing Division at (502) 564-6004.</p>			

FOR DEPARTMENT USE ONLY

PBM Coordinator Received:	
PBM Coordinator Initial Review Completed:	
Suspense/Objection Letter Sent:	
Response Received from PBM:	
Completion of PBM Health Requirements:	<p>_____</p> <p>Date of Health Review Completed</p> <p>_____</p> <p>Reviewer signature</p>