

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 806 KAR 17:575
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1) Provide a brief summary of:

(a) What this administrative regulation does: The administrative regulation expounds upon the Department of Insurance's oversight of the relationship between a pharmacy and pharmacy benefit manager as directed by KRS 304.17A-162. This administrative regulation provides further detail on the required internal and external complaint processes for pharmacy benefit managers. These appeals are available to pharmacists contesting the amount of a pharmacy benefit manager's maximum allowable cost payments received for prescriptions. The regulation sufficiently narrows the scope of the Department's review in the appeal process to ensure the pharmacy benefit manager has applied the appropriate standards required pursuant to KRS 304.17A-162. This administrative regulation requires a pharmacy benefit manager to provide the Department annual reports to allow for the identification of any issues in this specific process and determine any necessary Department action.

(b) The necessity of this administrative regulation: The administrative regulation is necessary to implement KRS 304.17A-162.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.17A-162 requires the Department to promulgate administrative regulations concerning specific aspects of the relationship between a pharmacy and a pharmacy benefit manager.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The administrative regulation clarifies the scope of the Department's review of maximum allowable cost prescription appeals. It also provides a reporting

obligation on behalf of pharmacy benefit managers to allow the Department to efficiently oversee pharmacy benefit managers and identify any areas of concern.

(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: The amendments to this administrative regulation address drafting requirement, as well as require all information be available electronically.

(b) The necessity of the amendment to this administrative regulation: In reviewing applications for Pharmacy Benefit Managers, the Department has addressed common questions, particularity related to the electronic format of the maximum allowable cost list and its searchability, so the amendments address the concerns raised.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.17A-162 requires the Department to promulgate administrative regulations concerning specific aspects of the relationship between a pharmacy and a pharmacy benefit manager. The amendments to this regulation clarify the beforementioned relationship, and the processes affiliated with them.

(d) How the amendment will assist in the effective administration of the statutes: These amendments clarify the regulation's intent, and require information to be available electronically which addresses many concerns that have been brought to the Department's attention.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Pharmacies, pharmacy benefit managers,

and insurers operating within the Commonwealth of Kentucky will be affected by this 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: The requirements imposed upon each of the entities are similar to existing requirements already found in other states. To comply with these Kentucky specific provisions, the pharmacy benefit managers will need to configure their operating systems in such a manner to allow pharmacies sufficient access to their maximum allowable cost price lists and weekly updates with the required information electronically. Pharmacy benefit managers will be required to maintain appeal data used in generating the annual reports.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The requirements established in this regulation are very similar to requirements already established in other states. The cost of compliance is minimal.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The parties will benefit from greater transparency in the prescription pricing process and the adoption of an official appeal process, with Department oversight, that will prevent parties from taking advantage of each other's position.

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

(a) Initially: This should not cost the Department as this is a current process included in the current budget.

(b) On a continuing basis: The Consumer Protection Division will continue to handle complaints submitted, and should have no increase of cost on the Department.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The current operational budget of the Department.

(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: There is no anticipated increase of fees.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering is not used as the regulation applies to all entities operating as pharmacy benefit managers.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

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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?
Kentucky Department of Insurance.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.17A-162.

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 will not generate any 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 will not generate any revenue for state or local government.

(c) How much will it cost to administer this program for the first year? The Department does not anticipate any additional cost.

(d) How much will it cost to administer this program for subsequent years? The Department anticipates the current personnel in the Department of Insurance will continue to investigate complaints.

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: