

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

806 KAR 17:290

Contact Person: Abigail Gall

Phone: 502-782-5260

Email: [abigail.gall@ky.gov](mailto:abigail.gall@ky.gov)

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the insurer requirements and procedures for the certification of independent review entities, and the process for initiating and conducting external review of utilization review decisions and step therapy exception request denials or step therapy internal appeal denials. This administrative regulation also establishes the disclosure requirements of the external review process to be included in the health benefit plan issued at the enrollment of a covered person.

(b) The necessity of this administrative regulation: The necessity of this administrative regulation is to set forth the processes and procedures required for the certification of independent review entities, as well as the process for initiating and conducting external review of utilization review decisions and step therapy exception request denials or step therapy internal appeal denials.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.17A-629 requires the commissioner to promulgate administrative regulations regarding the independent external review program and to provide forms for external review. KRS 304.17A-1631 requires the commissioner to promulgate administrative regulations regarding step therapy protocols and exceptions.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will comply by setting forth the requirements for independent review entity certification, how to initiate and conduct external reviews based on utilization review decisions, as well as step therapy exception request denials or step therapy internal appeal denials required by KRS 304.17A-629, KRS 304.17A-163, and KRS 304.17A-1631(1).

(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 subject step therapy exception denials and step therapy internal appeal denials to the external review processes of an independent review entity as required by KRS 304.17A-163 (SB 140 2022 Reg. Session). This filing also amends the incorporated forms to include step therapy exception request denials and step therapy internal appeal denials within independent review entities' certification, assignments, reporting procedures, and updates.

(b) The necessity of the amendment to this administrative regulation: The amendments to this regulation are to ensure proper enforcement of KRS 304.17A-163 and KRS 304.17A-1631 (SB 140 2022 Reg. Session)

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.17A-623 requires every insurer to have an external review process and KRS 304.17A-163 requires an insurer, health plan, private review agent, or pharmacy benefit manager to allow insureds the right to an external review based on step therapy exceptions and step therapy appeals denials issued.

(d) How the amendment will assist in the effective administration of the statutes: These amendments ensure that those independent review agencies/private review entities can appropriately address step therapy exceptions and step therapy appeals denials, that the external review process includes both of these circumstances, and that step therapy exception external reviews are reported on an annual basis.

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

The Department currently has 10 companies that hold certifications to perform Independent External Review cases in Kentucky. 1 company is currently enrolled in the application process.

(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: Independent External Review Entities regulated under this regulation will need to utilize the newly incorporated forms to adhere to the processes set forth in these administrative regulations and the related statutes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The cost should be minimal considering regulated entities have previously been required to report and should have the appropriate processes in place to comply.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Regulated entities which are in compliance with Acts Chapter 19 (2022 Reg. Session) will not incur penalties for non-compliance with the statutes.

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

(a) Initially: There is no cost associated with this administrative regulation.

(b) On a continuing basis: There is no cost associated with this administrative regulation.

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

(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, the Department does not foresee an increase in fees, but in the future, it may need to request an expansion of funding.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: No, this regulation does not establish any fees directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering is not applied because this regulation applies equally to all independent external review entities certified in this state.

## FISCAL NOTE

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Email: abigail.gall@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? The Department of Insurance as the implementer.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110(1), 304.17A-629, 304.17A-163, and 304.17A-1631.

(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? No revenue will be generated.

(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? No revenue will be generated.

(c) How much will it cost to administer this program for the first year? The Department is currently in the process of proposing a memorandum of agreement to contract with staff pharmacists or pharmacy consultants to assist with enforcing the provisions of KRS 304.17A-163 and 1631, and 806 KAR 17:280 and 17:290. The Department does not currently have the expertise on staff to review the clinical appropriateness of step-therapy protocols. Thus, the MOA is for a maximum of \$100,000 per year.

(d) How much will it cost to administer this program for subsequent years? The cost should be the same the subsequent year but could change depending on the renewal contract every two years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None expected

Expenditures (+/-): \$100,000

Other Explanation: N/A

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? No cost savings are associated with this regulation or amendments for regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? No cost savings are associated with this regulation or amendments for regulated entities

(c) How much will it cost the regulated entities for the first year? There is no cost expected.

(d) How much will it cost the regulated entities for subsequent years? There is no cost expected.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation: There is no cost associated with this administrative regulation and therefore no fiscal impact for regulated entities. The Department has reached out to the certified IREs in the state to see if they could perform the Step Therapy Exception external reviews and they indicated that they could (and that they currently provide these services for other states).

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]* At this time, the Department is not aware of a major economic impact.