

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

806 KAR 17:280

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(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes a process and requirements for the registration of insurers or private review agents, and utilization review process, including internal appeal decisions.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 304.17A-065, KRS 304.17A-609, and KRS 304.17A-613, which require the Commissioner to promulgate regulations regarding utilization review, internal appeal for the registration of insurers or private review agents and includes limited health service benefit plans and national accreditation organizations in the registration, utilization review, and internal appeal process. KRS 304.17A-1631 requires the commissioner to promulgate administrative regulations regarding step therapy protocols and exceptions.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110(1), authorizes the Commissioner to promulgate administrative regulations to aid in effectuation of the Insurance Code. KRS 304.17A-609 states that the department shall promulgate emergency administrative regulations regarding utilization review and internal appeal, including the specification of information required of insurers and private review agents. 304.17A-613, requires the department to establish the process for application review, fees, and registration of insurers and private review agents. 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 utilization review process, internal appeal, registration process, and step-therapy protocol processes required by 304.17A-609, 304.17A-613, and KRS 304.17A-6131.

(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: These amendments set forth the requirements for Internal Appeals of a Step Therapy Exception Denial and lay out the reporting process for insurers and pharmacy benefit managers to annually report to the Department the total number of step therapy exceptions denied/approved (and what category of services were denied/approved) on the Form HIPMC-STE-1 by March 31 of each year. Other amendments are technical in nature.

(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-1631 requires the department to set forth reporting requirements and processes for insurers and PBMs to report to the commissioner the number of step-therapy exception appeals and denials, and this administrative

regulation prescribes the format of the annual report and the process for filing an internal appeal for a step-therapy exception denial.

(d) How the amendment will assist in the effective administration of the statutes: These amendments set forth the reporting requirements defined in KRS 304.17A-1631 concerning step-therapy protocol exception appeals and denials.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect insurers offering health plans and limited health benefit plans, private review agents, and pharmacy benefit managers. There are 868 companies licensed to write health insurance here in Kentucky. This includes workers compensation insurers, life insurers, and MCOs. There are 54 licensed PBMs. This does not mean that all these entities are actively writing health plans; we have found that there are 12 insurers actively writing health benefit plans in the commercial market in Kentucky. The Department currently has 113 registered UR agents; some are registered as Private Review Agents, some as insurers, and some as Limited Health Service Organization reviewers.

(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: Regulated entities must allow insureds or a provider (on behalf of insureds) to request an internal appeal for a step therapy exception denial and the entity must provide a determination within 48-hours of receipt of the appeal. When providing written notice of the appeal determination decision, the entity must include specific information to the insured or provider as well as keep record of the correspondence for five (5) years. Regulated entities are also required to report the number of total step therapy exceptions denied/approved, and what category of services were denied/approved, for the previous plan year to the commissioner by March 31 of each year on the HIPMC-STE-1 Form.

(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 health insurers, pharmacy benefit managers, and private review agents.

## FISCAL NOTE

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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? 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-609, 304.17A-613, 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 for next year but could change depending on the terms of 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? None 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.

(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.