

PUBLIC PROTECTION CABINET
Department of Insurance
Health and Life and Managed Care Division
(Amendment)

806 KAR 17:290. Independent External Review Program.

RELATES TO: KRS 304.1-050, 304.2-100, 304.2-230, 304.2-310, 304.17A-005, 304.17A-505, 304.17A-600, 304.17A-617, 304.17A-621-304.17A-631, 304.17A-1631, 304.17A-168, 304.17A-535, 304.17A-607

STATUTORY AUTHORITY: KRS 304.2-110(1), 304.17A-629, 304.17A-163

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes the commissioner to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. KRS 304.17A-629 requires the department to promulgate administrative regulations regarding the Independent External Review Program, and KRS 304.17A-1631 requires the commissioner to promulgate administrative regulations regarding step therapy protocols and exceptions. This administrative regulation establishes the insurer requirements, 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 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 enrollment of a covered person.

Section 1. Definitions.

- (1) "Adverse determination" is defined by KRS 304.17A-600(1).
- (2) "Assign" or "assignment" means selection of an independent review entity by an insurer, and acceptance of a request to conduct an external review by an independent review entity.
- (3) "Authorized person" is defined by KRS 304.17A-600(2).
- (4) "Commissioner" is defined by KRS 304.1-050(1).
- (5) "Coverage denial" is defined by KRS 304.17A-617(1).
- (6) "Covered person" is defined by KRS 304.17A-600(4).
- (7) "Department" is defined by KRS 304.1-050(2).
- (8) "External review" is defined by KRS 304.17A-600(5).
- (9) "Financial hardship" means the:
 - (a) Gross income of the covered person is below 200 percent of the federal poverty level based upon family size as shown by a federal income tax return for the previous year; or
 - (b) Covered person's participation in one (1) of the following programs:
 1. National Prescription Drug Patient Assistance;
 2. Kentucky Transitional Assistance Program (K-TAP);
 3. Kentucky Medical Assistance Program; or
 4. Unemployment Insurance.
- (10) "Health Care Provider" or "Provider" is defined by KRS 304.17A-005(23).
- (11) "Independent review entity" is defined by KRS 304.17A-600(7).
- (12) "Insurer" is defined by KRS 304.17A-600(8).
- (13) "Reviewer" means an individual selected by the independent review entity to conduct an external review and make a recommended decision to the independent review entity.
- (14) "Step therapy exception" is defined by KRS 304.17A-163(1)(f).
- (15) "Step therapy protocol" is defined by KRS 304.17A-163(1)(g).

Section 2. Requirements of an Insurer.

(1) An insurer shall:

(a) Disclose to a covered person in a clear, concise, written format the following information concerning an external review:

1. At enrollment, the right to an external review in accordance with KRS 304.17A-505(1)(g);
2. The availability of an external review, including expedited external review, in the insurer's notice of an adverse determination in accordance with KRS 304.17A-623(1);
3. Instructions for initiating an external review in the internal appeal decision letter upholding an adverse determination, including:
 - a. Whether the appeal shall be in writing;
 - b. How to request and complete any necessary forms, including a medical records release form or written authorization of representation;
 - c. Applicable time frames;
 - d. The position and telephone number of a contact person who can provide additional information about an external review; and
 - e. Additional documentation that may be necessary to initiate the external review;
4. The right of a covered person to request an external review within sixty (60) days of receiving notice that, pursuant to KRS 304.17A-617(3)(d), the insurer has elected to afford an opportunity for external review;

(b) Allow a covered person, authorized person, or provider acting on behalf of and with the consent of a covered person, to submit an oral request, followed by a brief written request, for an expedited external review;

(c) Provide the following information relating to an external review in the policy or certificate of coverage issued to a covered person and upon request:

1. The circumstances under which the following types of external review shall be provided:
 - a. Nonexpedited external review in accordance with KRS 304.17A-623(3), (4) and (6), and (13); and
 - b. Expedited external review in accordance with KRS 304.17A-623(10), (11) and (12);
2. The filing fee for requesting an external review in accordance with KRS 304.17A-623(5);
3. Notice that the cost of an external review by an independent review entity shall be paid by the insurer in accordance with KRS 304.17A-625(5);
4. The procedure for submitting:
 - a. An oral request followed up by a brief written request, or a written request for an expedited external review;
 - b. A written request for a nonexpedited external review; and
 - c. Any specific forms required by the insurer to initiate an external review, including a written authorization of personal representation or a consent to release medical records form;
5. The time frame for:
 - a. Submitting a request for external review in accordance with KRS 304.17A-623(4);
 - b. Rendering a decision by an independent review entity in accordance with KRS 304.17A-623(12) and (13); and
 - c. Implementation of a decision of the independent review entity in accordance with KRS 304.17A-625(11) through (13);

6. A statement relating to the confidential treatment of medical records and information relating to the external review; and
 7. A statement of the availability of a complaint process through the department relating to:
 - a. A covered person's right to an external review in accordance with KRS 304.17A-623(8); and
 - b. The action of an independent review entity in accordance with KRS 304.17A-625(16);
 - (d) If an external review is requested by an authorized person or provider acting on behalf of a covered person, obtain the:
 1. Written authorization of representation; and
 2. Consent to release medical records to the independent review entity;
 - (e) Determine if an external review is warranted in accordance with KRS 304.17A-623(3) and (10), and notify the person who requested the external review of its determination within the following time periods:
 1. For expedited reviews, within twenty-four (24) hours of receipt of the request, pursuant to KRS 304.17A-623(11); or
 2. For nonexpedited reviews, within five (5) business days of receipt of the request;
 - (f) Upon a determination that an expedited external review is warranted:
 1. By telephone, request acceptance of assignment of the external review by an independent review entity, which was selected pursuant to KRS 304.17A-623(7) from a list of certified independent review entities maintained by the department at <http://insurance.ky.gov>; and
 2. Notify the independent review entity by telephone that the following documents shall be forwarded to the independent review entity in accordance with KRS 304.17A-623(11):
 - a. The written consent of the covered person authorizing release of medical records as required by KRS 304.17A-623(4);
 - b. Information to be considered as required by KRS 304.17A-625(1)(a); and
 - c. A completed External Review Information Face Sheet, HIPMC-IRE-6;
 - (g) Upon a determination that a nonexpedited external review is warranted:
 1. By telephone, request acceptance of assignment of the external review by an independent review entity which was selected pursuant to KRS 304.17A-623(7) from the list of certified independent review entities as identified in paragraph (f)1 of this subsection; and
 2. Within three (3) business days of assignment, deliver to the independent review entity the documentation as identified in paragraph (f)2 of this subsection;
 - (h) Upon assignment of an external review, complete and send to the department an Assignment of Independent Review Entity Form, HIPMC-IRE-2, within one (1) business day via email to DOI.UtilizationReview@ky.gov;
 - (i) Upon receipt of a decision relating to external review from an independent review entity, implement the decision in accordance with KRS 304.17A-625(11) through (13) and provide the department with a reprocessed explanation of benefits or other payment documentation showing the implementation of the overturned decision;
 - (j) Upon receipt of an invoice relating to an external review, pay the independent review entity within thirty (30) days;
 - (k) Maintain a written record of each external review for a period of not less than five (5) years pursuant to 806 KAR 2:070, Section 1; and
 - (l) Upon written notice of termination of an independent review entity pursuant to Section 3(21)(a) or (c) of this administrative regulation, reassign an external review in accordance with paragraphs (f) and (g) of this subsection.
- (2)

(a) If a request for external review is denied by an insurer, written notification shall be provided by the insurer to the person requesting the external review, which shall include:

1. The date the request for external review was received by the insurer;
2. A statement relating to the nature of the request;
3. The rationale of the insurer for denying the request;
4. A statement relating to the availability of review by the department if a dispute arises regarding the right to external review;
5. The toll-free telephone number of the department; and
6. The name and telephone number of a contact person who shall provide information relating to the denial of the request.

(b) If requested by the department, the insurer shall provide:

1. A copy of the written notification described in paragraph (a) of this subsection; and
2. Information or documentation that the insurer relied upon to deny the request for external review.

Section 3. Requirements of an Independent Review Entity. An independent review entity shall:

- (1) Accept a request for assignment unless:
 - (a) A conflict of interest exists;
 - (b) Confidentiality issues exist; or
 - (c) Due to circumstances beyond the control of the independent review entity, an appropriate reviewer becomes unavailable;
- (2) Upon receipt of a request for assignment from an insurer determine if a condition of subsection (1)(a) through (c) of this section exists;
- (3) Within twenty-four (24) hours of receipt of a request for assignment:
 - (a) Immediately provide verbal notification, followed by written notification to the insurer and department of the rejection of an assignment if a condition of subsection (1)(a) through (c) of this section exists; or
 - (b) Provide written notification to an insurer and the department via DOI.UtilizationReview@ky.gov of the acceptance of an assignment; and
- (4) Maintain a written record of:
 - (a) Whether the external review relates to an adverse determination or coverage denial, a step therapy exception denial, or step therapy internal appeal denial which requires resolution of a medical issue;
 - (b) The specific question or issue, as identified by the independent review entity, to be resolved by the external review; and
 - (c) Whether the external review is expedited or nonexpedited;
- (5) For each external review, obtain and maintain a signed statement of a reviewer that the reviewer has no conflict of interest;
- (6) Not limit the basis of an external review decision to the standards, criteria, and clinical rationale used by the insurer to make its decision pursuant to KRS 304.17A-625(1), (2), and (7);
- (7) Have a reviewer with expertise in:
 - (a) Health insurance benefits and contracts, who shall serve as a reviewer with a healthcare professional reviewer, in an external review of a coverage denial, step therapy exception request denial, or step therapy internal appeal denial which requires the resolution of a medical issue in accordance with KRS 304.17A-617(3)(d); and
 - (b) Health care, who shall:
 1. Conduct an external review of a step therapy exception request denial, step therapy internal appeal denial, or an adverse determination or coverage denial which

requires resolution of a medical issue in accordance with the requirements of KRS 304.17A-623~~[and an adverse determination which requires resolution of a medical issue]~~; and

2. Meet the following requirements:

- a. Hold active licensure in a state of the United States;
 - b. Have recent experience or familiarity with current body of knowledge and applicable specialty or subspecialty practice;
 - c. Have at least five (5) years of experience in the specialty or subspecialty of the external review; and
 - d. Hold current board certification by:
 - (i) The American Board of Medical Specialties if the reviewer is a medical doctor;
 - (ii) The American Osteopathic Association if the reviewer is a doctor of osteopathic medicine;
 - (iii) The American Board of Podiatric Surgery if the reviewer is a doctor of podiatric medicine; or
 - (iv) Other recognized health professional board pursuant to KRS 304.17A-627;
- (8) Establish criteria in accordance with KRS 304.17A-627 for:
- (a) Selection of a qualified reviewer, including the initial verification and reverification every three (3) years of credentials of the reviewer;
 - (b) Ensuring that an appropriate:
 1. Reviewer performs the external review; and
 2. Number of reviewers are used for the external review; and
 - (c) Ensuring that at least one (1) reviewer qualified in each medical specialty and subspecialty is available for external review;
 - (d) Provide a listing of the reviewers to the department including each reviewer's name, date of licensure, license number and specialty, including any subspecialty in accordance with KRS 304.17A-627(5) and (6);
- (9) Have a medical director or clinical director with professional postresidency experience in direct patient care who shall:
- (a) Hold a current license to practice medicine in a state of the United States;
 - (b) Provide guidance for the medical aspects of the external review process; and
 - (c) Oversee the medical aspects of the:
 1. Quality management program; and
 2. Reviewer credentialing program;
- (10) Establish and implement criteria for determination of the need for a time extension pursuant to KRS 304.17A-623(12) and (13);
- (11) Provide written notification of a decision as required by KRS 304.17A-625(6), which shall include the:
- (a) Title, professional license number, state of licensure and specialty or subspecialty certifications, if any, of the reviewer;
 - (b) Date the decision was rendered; and
 - (c) A statement that:
 1. The decision shall be final and binding on the insurer; and
 2. If dissatisfied with the decision, a comment, question, or complaint may be submitted in writing to the department;
- (12) Within two (2) business days of rendering a decision, provide written notification of the decision to the:
- (a) Covered person or authorized person, treating provider, and insurer; and
 - (b) Department via email at DOI.UtilizationReview@ky.gov by:
 1. Copying the department on the written notification to the covered person; and
 2. Completing an External Review Decision Notification Form, HIPMC-IRE-3;

- (13) Establish written policies and procedures for maintenance and the confidential treatment of external review records in accordance with KRS 304.17A-623(9), 806 KAR 3:210, and 806 KAR 3:230;
- (14) Maintain a written record of an external review for a minimum of five (5) years in accordance with 806 KAR 2:070, which shall include, as applicable:
- (a) All documentation relating to the external review pursuant to KRS 304.17A 625(1) (a);
 - (b) The independent review entity's decision regarding each issue identified in the external review request;
 - (c) The name, credentials, and specialty or subspecialty of the reviewer;
 - (d) Medical records and information considered during the review;
 - (e) References to any medical literature, research data, or national clinical criteria upon which the independent review entity's decision was based;
 - (f) A copy of the covered person's health benefit plan;
 - (g) A copy of the adverse determination or coverage denial, the step therapy exception request denial, or the step therapy internal appeal denial which requires resolution of a medical issue, and the internal appeal decision; and
 - (h) A copy of all correspondence and communication between the independent review entity, reviewer, and any other person regarding the external review, including a copy of the final external review decision letter;
- (15) Provide toll-free telephone access that:
- (a) Operates at a minimum from 9 a.m. until 5 p.m. of each business day in each time zone if the services under review are in dispute; and
 - (b) Allows for:
 - 1. Receiving after-hours requests for external review; and
 - 2. Acting upon expedited external review requests in accordance with KRS 304.17A-623(12);
- (16) If an external review function, or any portion of this function, is delegated or subcontracted to another person or organization, submit to the department:
- (a) Policies and procedures relating to oversight activities to ensure compliance with requirements of an independent review entity as established in KRS 304.17A-623 and 304.17A-625, and this section; and
 - (b) A copy of the delegation or subcontract agreement;
- (17) Establish and maintain a written quality assurance program in accordance KRS 304.17A-627, which shall be made available to the public upon request and shall include a written plan, which addresses:
- (a) Scope and objectives;
 - (b) Program organization;
 - (c) Monitoring and oversight mechanisms; and
 - (d) Evaluation and organizational improvement of external review activities, including:
 - 1. Objectives and approaches used in the monitoring and evaluation of external review activities, including the systematic evaluation of complaints for patterns and trends;
 - 2. The implementation of an action plan to improve or correct an identified problem; and
 - 3. The procedures to communicate the results of an action plan to its employees and reviewers, as applicable;
- (18) Submit a copy of any change to information provided on the Application for Certification of an Independent Review Entity, HIPMC-IRE-1, in writing to the department for approval. A change shall not become effective until approved by the commissioner;

- (19) Submit a new application for certification if requested by the department following notification of a material change in the application information as required by KRS 304.17A-627(2);
- (20) Establish a fee structure, to be available upon request, for each type or level of external review, including at a minimum, a fee for:
- (a) A completed external review of:
 - 1. A coverage denial, step therapy exception request denial, or step therapy internal appeal denial which requires resolution of a medical issue; and
 - 2. An adverse determination; and
 - (b) An incomplete external review;
- (21) Immediately terminate an external review and provide notice by telephone, followed by a written notification to the department and, if appropriate, the insurer requesting the external review if:
- (a) A conflict of interest or confidentiality issue is discovered at any time during the external review process;
 - (b) A reversal of a coverage denial, step therapy exception request denial, step therapy internal appeal denial, or adverse determination is received in writing from the insurer; or
 - (c) The independent review entity or a reviewer becomes unavailable for reasons beyond the control of the independent review entity, including acts of God, natural disasters, epidemics, strikes or other labor disruptions, war, civil disturbances, riots, or complete or partial disruptions of facilities;
- (22) If more than one (1) reviewer is utilized in making a decision:
- (a) Render an overall decision based upon the majority decision of the reviewers; or
 - (b) If the reviewers are evenly split as to whether the recommended or requested health care service or treatment shall be covered, request an additional reviewer to make a binding majority decision;
- (23) Implement a written policy and procedure for each aspect of an external review process, including:
- (a) Processing of the request for assignment of an external review from an insurer;
 - (b) Receipt and maintenance of medical records and information from insurer;
 - (c) Ensuring access to appropriate qualified reviewers pursuant to subsection (8) of this section;
 - (d) Ensuring the credentialing, selection, and notification of a reviewer who performs an external review;
 - (e) Rendering a timely decision and issuing notification of the decision;
 - (f) Ongoing monitoring and evaluation of the performance of a reviewer;
 - (g) Monitoring and oversight of a delegated external review function, if any;
 - (h) Billing and collection of fees for external review, including:
 - 1. Filing fee of the covered person; and
 - 2. Cost of external review for the insurer;
 - (i) Collecting and reporting data;
 - (j) Termination of external review; and
 - (k) Response to a request for information relating to a complaint filed with the department; and
- (24)
- (a) Conduct annually, a program for training reviewers, which:
 - 1. Provides information relating to the requirements of the Kentucky Independent External Review Program; and
 - 2. Describes the policies and procedures of the independent review entity, as applicable; and
 - (b) Provide a written record of the training to the department, upon request.

Section 4. Application Process for Certification to Perform External Reviews.

- (1) To perform an external review, an independent review entity shall be certified in accordance with requirements established in KRS 304.17A-627, and this administrative regulation.
- (2) To be certified to perform an external review, an independent review entity shall:
 - (a) Complete and submit to the department, an Application for Certification of an Independent Review Entity, HIPMC-IRE-1;
 - (b) Submit a fee with the application for certification as required by Section 5 of this administrative regulation; and
 - (c) Enclose with the application for certification, written documentation which supports compliance with the requirements of an independent review entity established in KRS 304.17A-627 and Section 3 of this administrative regulation.
- (3) In renewing a certification, an independent review entity shall submit an application for certification to the department at least ninety (90) days prior to expiration of the current certification.

Section 5. Fees.

- (1) Department fees.
 - (a) An application for certification as an independent review entity shall be submitted with \$500.
 - (b) Pursuant to KRS 304.17A-627(2), a change in application information after certification shall be submitted with fifty (50) dollars.
 - (c) Fees submitted to the department shall be made payable to the Kentucky State Treasurer.
- (2) Independent review entity fees.
 - (a)
 1. Except for a fee which meets the criteria established in HIPMC-IRE-5, Approval of an External Review Fee in Excess of \$800, the total fee charged for an external review shall not exceed \$800; and
 2. The fee proposed by the independent review entity in excess of \$800 shall be submitted to the department for approval prior to billing the insurer with the justification defined in HIPMC-IRE-5, Approval of an External Review Fee in Excess of \$800.
 - (b) The twenty-five (25) dollar filing fee to be paid by the covered person shall:
 1. Be billed by the independent review entity upon assignment; or
 2. Be waived if it creates a financial hardship pursuant to KRS 304.17A-623(5).

Section 6. Department Review of Application for Certification or Change in Information Provided on the Application.

- (1) Upon review of an application for certification or a change in information provided on the application, the department shall:
 - (a) Notify the applicant of any missing or necessary information;
 - (b) Identify and request submission of the information identified in paragraph (a) of this subsection within thirty (30) days;
 - (c) If requested information is not provided to the department within the time frame established in paragraph (b) of this subsection:
 1. Disapprove the application for certification or the change of information provided on the application; and
 2. Not refund the applicable fee submitted in accordance with Section 5(1) of this administrative regulation; and
 - (d) Approve or deny certification or a change to information provided on the application of an independent review entity within ninety (90) days of submission.

(2) An independent review entity certification shall expire on the second anniversary of the certification date unless the certification is renewed by the independent review entity, which submits a new application for certification in accordance with Section 4(2) of this administrative regulation.

Section 7. Denial, Decertification, or Suspension Hearing Procedure. Upon the denial of certification, decertification, or suspension of a certification, the department shall:

- (1) Give written notice of its action; and
- (2) Advise the applicant or certificate holder that a request for a hearing may be filed in accordance with KRS 304.2-310.

Section 8. Independent Review Entity Complaint Process.

(1) A copy of the complaint filed pursuant to KRS 304.17A-625(16) and a letter from the department requesting a written response to the complaint shall be sent to the independent review entity.

(2) Within ten (10) business days of receipt of the letter from the department, the independent review entity shall submit a written response to the department, including the following:

- (a) Information relating to the complaint;
- (b) If applicable, corrective actions to address the complaint, including time frames for actions; and
- (c) A mechanism to evaluate the corrective action, if applicable.

(3) Upon receipt of the written response of the independent review entity, the department shall:

- (a) If applicable, take action pursuant to KRS 304.17A-625(16); and
- (b) Notify the complainant of the department's findings and action taken, if any.

Section 9. Department Investigations. The commissioner may conduct an investigation of an independent review entity pursuant to KRS 304.2-100 and 304.2-230.

Section 10. Reporting Requirements. An independent review entity shall complete and submit to the department by March 31 of each year for the previous calendar year, the Annual Independent Review Entity Report Form, HIPMC-IRE-4.

Section 11. Cessation of Participation. Upon a decision to terminate participation in the independent external review program as established in KRS 304.17A-621, an independent review entity shall:

- (1) Immediately notify the department in writing of its decision to cease accepting new assignments; and
- (2) Except for reasons beyond its control, submit the following to the department for approval at least thirty (30) days prior to termination:
 - (a) Written notification of the termination, including:
 1. Date of termination; and
 2. Number of pending external reviews with corresponding assignment dates; and
 - (b) A written action plan for terminating participation.

Section 12. Incorporated by Reference.

- (1) The following material is incorporated by reference:
 - (a) Form HIPMC-IRE-1, "Application for Certification of an Independent Review Entity", 10/2022 edition~~[09/2020 edition]~~;
 - (b) Form HIPMC-IRE-2, "Assignment of Independent Review Entity Form", 10/2022 edition~~[09/2020 edition]~~;
 - (c) Form HIPMC-IRE-3, "External Review Decision Notification Form", 09/2020 edition;

(d) Form HIPMC-IRE-4, "Annual Independent Review Entity Report Form", 10/2022 edition~~[09/2020 edition]~~;

(e) Form HIPMC-IRE-5, "Approval of an External Review Fee in Excess of \$800", 09/2020 edition; and

(f) Form HIPMC-IRE-6, "External Review Information Face Sheet", 10/2022 edition~~[09/2020 edition]~~.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Insurance, The Mayo-Underwood Building, 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the department's Web site at <https://insurance.ky.gov/ppc/CHAPTER.aspx>.

SHARON P. CLARK, Commissioner

RAY A. PERRY, Secretary

AGENCY APPROVED: October 13, 2022

FILED WITH LRC: October 13, 2022 at 3:54 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 a.m. on December 28, 2022 at 500 Mero Street, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative p.m. on December 31, 2022. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below. Contact Person: Abigail Gall, Title: Executive Advisor, Address: 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email abigail.gall@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Abigail Gall

(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?

Tiering is not applied because this regulation applies equally to all independent external review entities certified in this state.

FISCAL NOTE

(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.