

PUBLIC PROTECTION CABINET
Department of Insurance
Health Life and Managed Care Division
(Amended at ARRS Committee)

806 KAR 17:280. Registration, utilization review, and internal appeal.

RELATES TO: KRS 217.211, 304.2-140, 304.2-310, 304.17-412, 304.17A-005, 304.17A-163, 304.17A-1631, 304.17A.167, 304.17A-168, 304.17A-535, 304.17A-600, 304.17A-607, 304.17A-619, 304.17A-623, 304.17C-010, 304.17C-030, 304.18-045, 304.32-147, 304.32-330, 304.38-225, 304.47-050

STATUTORY AUTHORITY: KRS 304.2-110(1), 304.17A-609, 304.17A-613, 304.17A-1631

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes the Commissioner to promulgate reasonable 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-609 requires the department to promulgate administrative regulations regarding utilization review and internal appeal and KRS 304.17A-1631 requires the commissioner to promulgate administrative regulations regarding step therapy protocols and exceptions. KRS 304.17A-613 requires the department to promulgate administrative regulations to develop a process for the registration of insurers or private review agents. This administrative regulation establishes requirements for the registration of insurers or private review agents, and the utilization review process, including internal appeal of decisions and step therapy exception request denials.

Section 1. Definitions.

- (1) "Adverse determination" is defined by KRS 304.17A-600(1).
- (2) "Authorized person" is defined by KRS 304.17A-600(2).
- (3) "Board" means one (1) of the following governing bodies:
 - (a) The American Board of Medical Specialties;
 - (b) The American Osteopathic Association; or
 - (c) The American Board of Podiatric Surgery.
- (4) "Coverage denial" is defined by KRS 304.17A-617(1).
- (5) "Department" means Department of Insurance.
- (6) "Enrollee" is defined by KRS 304.17C-010(2).
- (7) "Health benefit plan" is defined by KRS 304.17A-005(22).
- (8) "Health Care Provider" or "provider" is defined in KRS 304.17A-005(23) and includes pharmacy as required under 806 KAR 17:580.
- (9) "Insurer" is defined by KRS 304.17A-005(29).
- (10) "Internal appeals process" is defined by KRS 304.17A-600(9).
- (11) "Limited health service benefit plan" is defined by KRS 304.17C-010(5).
- (12) "Nationally recognized accreditation organization" is defined by KRS 304.17A-600(10).
- (13) "Notice of coverage denial" means a letter, a notice, or an explanation of benefits statement advising of a coverage denial.
- (14) "Policies and procedures" means the documentation which outlines and governs the steps and standards used to carry out functions of a utilization review program.
- (15) "Private review agent" is defined by KRS 304.17A-600(11).
- (16) "Registration" is defined by KRS 304.17A-600(14).
- (17) "Step therapy exception" is defined in KRS 304.17A-163(1)(f).
- (18) "Step therapy protocol" is defined in KRS 304.17A-163(1)(g).

(19) "Utilization review" is defined by KRS 304.17A-600(17).

(20) "Utilization review plan" is defined by KRS 304.17A-600(18).

Section 2. Registration Required for Utilization Review.

(1) The department shall issue a registration to an applicant who has met the requirements of KRS 304.17A-600 through 304.17A-619 and KRS 304.17A-623, if applicable, and Sections 2 through 11 of this administrative regulation.

(2) An applicant seeking registration to provide or perform utilization review shall:

(a) Submit an application to the department as required by Section 4 of this administrative regulation; and

(b) Pay an application fee as required by Section 3 of this administrative regulation.

(3) If an insurer, private review agent, or other registered UR entity desires a renewal of registration to perform utilization review, an application for renewal of registration shall be submitted to the department at least ninety (90) days prior to expiration of the current registration.

Section 3. Fees.

(1) An application for registration shall be accompanied by a fee of \$1,000.

(2) A submission of changes to utilization review policies or procedures to the department shall be accompanied by a fee of fifty (50) dollars.

(3) A fee as established in subsection (1) or (2) of this section shall be made payable to the Kentucky State Treasurer.

Section 4. Application Process for Utilization Review.

(1) An applicant for registration shall complete and submit to the department an application, HIPMC-UR-1 and HIPMC-MD-1, and except as provided in subsection (3) of this section, documentation to support compliance with KRS 304.17A-600 through 304.17A-623, as applicable, including:

(a) A utilization review plan;

(b) The identification of criteria used for all services requiring utilization review;

(c) Types and qualifications of personnel, employed directly or under contract, performing utilization review in compliance with KRS 304.17A-607, including names, addresses, and telephone numbers of the medical director and contact persons for questions regarding the filing of the application;

(d) A toll-free telephone number to contact the insurer, limited health service benefit plan, private review agent, or other registered UR entity as required by KRS 304.17A-607(1)(e) and 304.17A-609(3);

(e) A copy of the policies and procedures required by:

1. KRS 304.17A-163;

2. KRS 304.17A-1631;

3. KRS 304.17A-167;

4. KRS 304.17A-603;

5. KRS 304.17A-607, and including the policies and procedures required by KRS 304.17A-607(1)(f) and (i); and

6. KRS 304.17A-609(4);

(f) A copy of the policies and procedures by which:

1. A limited health service benefit plan provides a notice of review decision which complies with KRS 304.17A-607(1)(h) to (j) and includes:

a. Date of service or preservice request date;

b. Date of the review decision;

c. Date and time the step therapy exception request was received;

d. Date and time the step therapy exception request was completed; and

e. Instructions for filing an internal appeal; or

2. An insurer, private review agent, or other registered UR entity provides a notice of review decision, which complies with KRS 304.17A-607(1)(h) to (j) and 806 KAR 17:230, and includes:
 - a. Date of service or preservice request date;
 - b. Date of the review decision;
 - c. Date and time the step therapy exception request was received;
 - d. Date and time the step therapy exception request was completed; and
 - e. Instructions for filing an internal appeal, including information concerning:
 - (i) The availability of an expedited internal appeal and a concurrent expedited external review;
 - (ii) For an adverse determination, the right to request that the appeal be conducted by a board eligible or certified physician pursuant to KRS 304.17A-617(3)(b); and
 - (iii) The insurer's contact information for conducting appeals, which shall include an address and direct ten (10) digit telephone number, and which shall be bolded and more prominently displayed than the contact information of the department; and
 - d. Information relating to the availability of:
 - (i) A review of a coverage denial by the department following completion of the internal appeal process; or
 - (ii) A review of an adverse determination by an independent review entity following completion of the internal appeal process, in accordance with KRS 304.17A-623;
- (g) If a part of the utilization review process is delegated, a description of the:
 1. Delegated function;
 2. Entity to whom the function was delegated, including name, address, and telephone number; and
 3. Monitoring mechanism used by the insurer, private review agent, or other registered UR entity to assure compliance of the delegated entity with paragraph (f) of this subsection;
- (h) A sample copy of an electronic or written notice of review decision, which complies with paragraph (f) of this subsection;
- (i) A copy of the policies and procedures by which a covered person, authorized person, or provider may request an appeal of an adverse determination, or coverage denial in accordance with KRS 304.17A-617, including:
 1. The method by which an appeal may be initiated, including:
 - a. An oral request followed by a brief written request, or a written request for an expedited internal appeal;
 - b. A written request for a nonexpedited internal appeal; and
 - c. If applicable, the completion of a specific form, including a medical records release consent form with instructions for obtaining the required release form;
 2. Time frames for:
 - a. Conducting a review of an initial decision; and
 - b. Issuing an internal appeal decision;
 3. Procedures for coordination of expedited and nonexpedited appeals;
 4. Qualifications of the person conducting internal appeal of the initial decision in accordance with KRS 304.17A-617(3)(b);
 5. Information to be included in the internal appeal determination in accordance with KRS 304.17A-617(3)(b), including the:
 - a. Title and, if applicable, the license number, state of licensure, and certification of specialty or subspecialty of the person making the internal appeal determination;

- b. Clear, detailed decision; and
 - c. Availability of an expedited external review of an adverse determination; and
- 6. A sample copy of the internal appeal determination in compliance with paragraph (i)5 of this subsection; and
- (j) A copy of the policies and procedures, which:
 - 1. Address and ensure the confidentiality of medical information in accordance with KRS 304.17A-609(5), 806 KAR 3:210, and 806 KAR 3:230;
 - 2. Comply with the requirements of KRS 304.17A-615 if the insurer, private review agent, or other registered UR entity fails to:
 - a. Provide a timely utilization review decision; or
 - b. Be accessible, as determined by verifiable documentation of a provider's attempts to contact the insurer, private review agent, or other registered UR entity, including verification by:
 - (i) Electronic transmission records; or
 - (ii) Telephone company logs;
 - 3. Comply with the requirements of KRS 304.17A-619, regarding the submission of new clinical information prior to the initiation of the external review process;
 - 4. Address and ensure consistent application of review criteria for all services requiring utilization review; and
 - 5. Comply with the requirements of KRS 304.17A-607(1)(k), as applicable.
- (2) Upon review of an application for registration, submitted changes to utilization review policies and procedures in accordance with KRS 304.17A-607(3), or submitted changes to internal appeals policies and procedures in accordance with KRS 304.17A-617(3), the department shall:
 - (a) Inform the applicant if supplemental information is needed;
 - (b) Identify and request that supplemental information be submitted to the department within thirty (30) days;
 - (c) If requested information is not provided to the department within the timeline established in paragraph (b) of this subsection:
 - 1. Deny the application for registration or proposed changes to utilization review or internal review policies and procedures; and
 - 2. Not refund the application or filing fee; and
 - (d) Approve or deny registration or proposed changes to utilization review or internal review policies and procedures.
- (3) To be registered to perform utilization review in Kentucky, an applicant who holds accreditation or certification in utilization review by a nationally recognized accreditation organization in accordance with KRS 304.17A-613(10) shall be required to submit with its completed application to the department:
 - (a)
 - 1. Evidence of current accreditation or certification in utilization review, including an expiration date; and
 - 2. Documentation to demonstrate compliance with the requirements of KRS 304.17A-613(10) and that the standards of the accreditation organization sufficiently meet the minimum requirements in subsection (1) of this section.
 - (b) If the national accreditation standard does not meet all the requirements as established in subsection (1) of this Section, then the applicant shall submit the additional information required under subsection (1) of this section.

Section 5. Denial or Revocation Hearing Procedure. Upon denial of an application for registration, or suspension or revocation of an existing registration, the department shall:

- (1) Give written notice of its action; and

(2) Advise the applicant or registration holder that if dissatisfied, a hearing may be requested and filed in accordance with KRS 304.2-310.

Section 6. Complaints Relating to Utilization Review.

(1) A written complaint regarding utilization review shall be reviewed by the department in accordance with KRS 304.17A-613(8).

(2) Upon receiving a copy of the complaint, an insurer, private review agent, or other registered UR entity shall provide a response in accordance with KRS 304.17A-613(8) (a), including:

(a) Any information relating to the complaint;

(b) All correspondence or communication related to the denial between any of the parties, including the insurer, the member, provider, and private review agent; and

(c) Corrective actions to address the complaint, if applicable, including a timeframe for each action.

(3) Within thirty (30) days of implementation of a corrective action, as identified in subsection (2) of this section, an insurer, private review agent, or other registered UR entity shall notify the department in writing of the implementation of the corrective action.

(4) If an insurer, private review agent, or other registered UR entity fails to comply with this section, the department may impose a penalty in accordance with KRS 304.2-140.

(5) The number, recurrence, and type of complaints, as identified in subsection (1) of this section, shall be considered by the department in reviewing an application for registration pursuant to KRS 304.17A-613(9).

Section 7. Internal Appeals for a Health Benefit Plan. In addition to the requirements of KRS 304.17A-617, and as part of an internal appeals process, an insurer, private review agent, or other registered UR entity shall:

(1) Allow a covered person, authorized person, or provider acting on behalf of a covered person to request an internal appeal at least sixty (60) days following receipt of a denial letter;

(2) Provide written notification of an internal appeal determination decision as required by KRS 304.17A-617(3)(a) and (d), which shall include the:

(a) Title and, if applicable, the license number, state of licensure and specialty or subspecialty certifications of the person performing the review;

(b) Elements required in a letter of denial in accordance with 806 KAR 17:230, Sections 4 and 5, if applicable;

(c) Position and telephone number of a contact person who may provide information relating to the internal appeal;

(d) Date of service or preservice request date; and

(e) Date of the internal appeal decision;

(3) Maintain written records of an internal appeal, including the:

(a) Reason for the internal appeal;

(b) Date that the internal appeal was received by the insurer, private review agent, or other registered UR entity, including the date any necessary or required authorizations were received;

(c) Date of the internal appeal decision;

(d) Internal appeal decision; and

(e) Information required by Section 4(1)(i)5 of this administrative regulation; and

(4) Retain a record of an internal appeal decision for five (5) subsequent years in accordance with 806 KAR 2:070.

Section 8. Internal Appeals for a Limited Health Service Benefit Plan.

(1) An insurer offering a limited health service benefit plan shall have an internal appeals process which shall:

(a) Be disclosed to an enrollee in accordance with KRS 304.17C-030(2)(g); and

(b) Include provisions, which:

1. Allow an enrollee, authorized person, or provider acting on behalf of the enrollee to request an internal appeal within at least sixty (60) days of receipt of a notice of adverse determination or coverage denial or if applicable, a step therapy exception denial; and

2. Require the limited health service benefit plan to provide a written internal appeal determination within thirty (30) days following receipt of a request for an internal appeal.

(2) A notice of adverse determination or coverage denial or if applicable, a step therapy exception denial shall include a disclosure of the availability of the internal appeals process.

Section 9. Internal Appeals for a Step Therapy Exception Denial. In addition to the requirements of KRS 304.17A-617, and as part of the internal appeals process for a step therapy exception denial, an insurer, private review agent, or pharmacy benefit manager shall:

(1) Allow a covered person or provider acting on behalf of a covered person to request an internal appeal of a step therapy exception denial;

(2) Require the insurer, private review agent, or pharmacy benefit manager to provide a written internal appeal determination within forty-eight (48) hours following receipt of a request for an internal appeal of a step therapy exception denial;

(3) Provide written notification of an internal appeal determination decision as required by KRS 304.17A-617(3)(a) and (d) and KRS 304.17A-163(4)(a), which shall include the:

(a) Title and, if applicable, the license number, state of licensure and specialty or subspecialty certifications of the person performing the review;

(b) Elements required in a letter of denial in accordance with 806 KAR 17:230, Sections 4 and 5, if applicable;

(c) Position and telephone number of a contact person who may provide information relating to the internal appeal;

(d) Date of service or preservice request date;

(e) Date and time the step therapy exception internal appeal was received;

(f) Date and time of the step therapy exception internal appeal decision;

(g) Maintain written records of a step therapy exception internal appeal, including the:

1. Reason for the step therapy exception internal appeal;

2. Date that the step therapy exception internal appeal was received by the insurer, private review agent, or other registered UR entity, including the date any necessary or required authorizations were received;

3. [The] Clinical review criteria used to make the step therapy exception appeal determination;

4. Date and time of the step therapy exception internal appeal decision;

5. Step therapy exception internal appeal decision; and

6. Information required by Section 4(1)(i)5. of this administrative regulation; and

(4) Retain a record of a step therapy exception internal appeal decision for five (5) years from the date of decision in accordance with 806 KAR 2:070.

Section 10. Reporting Requirements. By March 31 of each calendar year, an insurer, private review agent, or other registered UR entity shall complete and submit to the department a HIPMC-UR-2, and a HIPMC-STE-1 for the previous calendar year.

Section 11. Maintenance of Records. An insurer, private review agent, or other registered UR entity shall maintain documentation to assure compliance with KRS 304.17A-163, 304.17A-1631, 304.17A-600 through 304.17A-619, 304.18-045, 304.32-147, 304.32-330, 304.38-225, and 304.47-050, including:

- (1) Proof of the volume of reviews conducted per the number of review staff broken down by staff answering the phone;
- (2) Information relating to the availability of physician consultation;
- (3) Information which supports that based on call volume, the insurer, private review agent, or other registered UR entity has sufficient staff to return calls in a timely manner;
- (4) Proof of the volume of phone calls received on the toll-free phone number per the number of phone lines;
- (5) Telephone call abandonment rate; and
- (6) Proof of the response time of insurer, private review agent, or other registered UR entity for returned phone calls to a provider if a message is taken.

Section 12. Cessation of Operations to Perform Utilization Review.

- (1) Upon a decision to cease utilization review operations in Kentucky, an insurer, private review agent, or other registered UR entity shall submit the following to the department thirty (30) days or as soon as practicable prior to ceasing operations:
 - (a) Written notification of the cessation of operations, including the proposed date of cessation and the number of pending utilization review decisions with projected completion dates; and
 - (b) A written action plan for cessation of operations, which shall be subject to approval by the department prior to implementation.
- (2) Annual reports required pursuant to Section 9 of this administrative regulation shall be submitted to the department within thirty (30) calendar days of ceasing operations.

Section 13. Incorporated by Reference.

- (1) The following material is incorporated by reference:
 - (a) Form HIPMC-UR-1, "Utilization Review Registration Application", 01/2023 edition;
 - (b) Form HIPMC-UR-2, "Annual Utilization Review (UR) Report Form", 09/2020 edition;
 - (c) Form HIPMC-MD-1, "Medical Director Report Form", 09/2020 edition; and
 - (d) Form HIPMC-STE-1, "Step Therapy Annual Report", 01/2023 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 pm. This material is also available on the department's Web site at <https://insurance.ky.gov/ppc/CHAPTER.aspx>.

(806 KAR 017:280. 27 Ky.R. 1698, 2453; eff. 3-19-2001; 29 Ky.R. 1375, 1845, 2099; eff. 2-16-2003; 31 Ky.R. 435, 708; eff. 11-5-2004; TAm eff. 8-9-2007; 35 Ky.R. 654, eff. 12-5-2008; Cert eff. 2-26-2020; 49 Ky.R. 1174, 1766; eff. 5-30-2023.)

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