

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

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

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) ~~[(11)]~~ "Nationally recognized accreditation organization" is defined by KRS 304.17A-600(10).
- (13) ~~[(12)]~~ "Notice of coverage denial" means a letter, a notice, or an explanation of benefits statement advising of a coverage denial.
- (14) ~~[(13)]~~ "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) ~~[(14)]~~ "Private review agent" is defined by KRS 304.17A-600(11).
- (16) ~~[(15)]~~ "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) ~~((16))~~ "Utilization review" is defined by KRS 304.17A-600(17)).

(20) ~~((17))~~ "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 that 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 or private review agent 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, or private review agent, 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. ~~[By]~~ KRS 304.17A-167;

4. ~~[2.] [By]~~ KRS 304.17A-603;

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

6. ~~[4.] [By]~~ 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; and

c. Instructions for filing an internal appeal; or

2. An insurer or private review agent 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. 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(2)(c); 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 address~~; 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 or private review agent 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(2)(c);
 - 5. Information to be included in the internal appeal determination in accordance with KRS 304.17A-617(2)(e), 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 requirements of KRS 304.17A-615 if the insurer or private review agent 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 or private review agent, including verification by:
 - (i) Electronic transmission records; or
 - (ii) Telephone company logs;
 3. Comply with 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 requirements of KRS 304.17A-607(1)(k), as applicable.
- (2) Upon review of an application for registration, ~~for~~ 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) In order to be registered to perform utilization review in Kentucky, an applicant ~~who~~which 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 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 or private review agent 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 or private review agent shall notify the department in writing of the implementation of the corrective action.
- (4) If an insurer or private review agent 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 or private review agent 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(2)(a), (b), and (e), 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 or private review agent, 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(2)(a), (b), and (e) 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; and
 - (e) Date and time the internal appeal was received;
 - (f) Date and time of the internal appeal decision;
 - (g) Maintain written records of an internal appeal, including the:
 1. Reason for the internal appeal;
 2. Date that the internal appeal was received by the insurer or private review agent, 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 of the internal appeal decision;
 5. Internal appeal decision; and
 6. 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) years from the date of decision in accordance with 806 KAR 2:070.

Section 10. ~~Section 9.~~ Reporting Requirements. By March 31 of each calendar year, an insurer or private review agent shall complete and submit to the department a HIPMC-UR-2, and a HIPMC-STE-1~~7~~ for the previous calendar year.

Section 11. ~~Section 10.~~ Maintenance of Records. An insurer or private review agent 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 or private review agent 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 or private review agent for returned phone calls to a provider if a message is taken.

Section 12. ~~[Section 11.]~~ Cessation of Operations to Perform Utilization Review.

(1) Upon a decision to cease utilization review operations in Kentucky, an insurer or private review agent 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. ~~[Section 12.]~~ Incorporated by Reference.

(1) The following material is incorporated by reference:

(a) Form HIPMC-UR-1, "Utilization Review Registration Application", 10/2022~~[09/2020]~~ edition;

(b) Form HIPMC-UR-2, "Annual Utilization Review (UR) Report Form", 09/2020 edition;~~[and]~~

(c) Form HIPMC-MD-1, "Medical Director Report Form", 09/2020 edition; and

(d) Form HIPMC-STE-1, "Step Therapy Annual Report", 10/2022 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>.

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 regulation. Written comments shall be accepted through 11:59 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, Executive Advisor, 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 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?

Tiering is not applied because this regulation applies equally to all health insurers, pharmacy benefit managers, and private review agents.

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-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.