[Ky. Rev. Stat. §§ 304.17A-600 through 304.17A-633.]

§§ 304.17A-600 through 304.17A-633: Utilization Reviews

304.17A-600. Definitions for KRS 304.17A-600 to 304.17A-633.

As used in KRS 304.17A-600 to 304.17A-633:

(1) (a) "Adverse determination" means a determination by an insurer or its designee that the health care services furnished or proposed to be furnished to a covered person are:

1. Not medically necessary, as determined by the insurer, or its designee or experimental or investigational, as determined by the insurer, or its designee; and
2. Benefit coverage is therefore denied, reduced, or terminated.

(b) "Adverse determination" does not mean a determination by an insurer or its designee that the health care services furnished or proposed to be furnished to a covered person are specifically limited or excluded in the covered person's health benefit plan;

(2) "Authorized person" means a parent, guardian, or other person authorized to act on behalf of a covered person with respect to health care decisions;

(3) "Concurrent review" means utilization review conducted during a covered person's course of treatment or hospital stay;

(4) "Covered person" means a person covered under a health benefit plan;

(5) "External review" means a review that is conducted by an independent review entity which meets specified criteria as established in KRS 304.17A-623, 304.17A-625, and 304.17A-627;

(6) "Health benefit plan" has the same meaning as in KRS 304.17A-005, except that for purposes of KRS 304.17A-600 to 304.17A-633, the term includes short-term coverage policies;

(7) "Independent review entity" means an individual or organization certified by the department to perform external reviews under KRS 304.17A-623, 304.17A-625, and 304.17A-627;

(8) "Insurer" means any of the following entities authorized to issue health benefit plans as defined in subsection (6) of this section: an insurance company, health maintenance organization; self-insurer or multiple employer welfare arrangement not exempt from state regulation by ERISA; provider-sponsored integrated health delivery network; self-insured employer-organized association; nonprofit hospital, medical-surgical, or health service corporation; or any other entity authorized to transact health insurance business in Kentucky;

(9) "Internal appeals process" means a formal process, as set forth in KRS 304.17A- 617, established and maintained by the insurer, its designee, or agent whereby the covered person, an authorized person, or a provider may contest an adverse determination rendered by the insurer, its designee, or private review agent;

(10) "Nationally recognized accreditation organization" means a private nonprofit entity that sets national utilization review and internal appeal standards and conducts review of insurers, agents, or independent review entities for the purpose of accreditation or certification. Nationally recognized accreditation organizations shall include the Accreditation Association for Ambulatory Health Care (AAAHC), the National Committee for Quality Assurance (NCQA), the American Accreditation Health Care Commission (URAC), the Joint Commission, or any other organization identified by the department;

(11) "Private review agent" or "agent" means a person or entity performing utilization review that is either affiliated with, under contract with, or acting on behalf of any insurer or other person providing or administering health benefits to citizens of this Commonwealth. "Private review agent" or "agent" does not include an independent review entity which performs external review of adverse determinations;

(12) "Prospective review" means a utilization review that is conducted prior to the provision of health care services. "Prospective review" also includes any insurer's or agent's requirement that a covered person or provider notify the insurer or agent prior to providing a health care service, including but not limited to prior authorization, step therapy, preadmission review, pretreatment review, utilization, and case management;

(13) "Qualified personnel" means licensed physician, registered nurse, licensed practical nurse, medical records technician, or other licensed medical personnel who through training and experience shall render consistent decisions based on the review criteria;

(14) "Registration" means an authorization issued by the department to an insurer or a private review agent to conduct utilization review;

(15) "Retrospective review" means utilization review that is conducted after health care services have been provided to a covered person. "Retrospective review" does not include the review of a claim that is limited to an evaluation of reimbursement levels, or adjudication of payment;

(16) (a) "Urgent health care services" means health care or treatment with respect to which the application of the time periods for making nonurgent determination:

1. Could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function; or

2. In the opinion of a physician with knowledge of the covered person's medical condition, would subject the covered person to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review.

(b) Urgent health care services include all requests for hospitalization and outpatient surgery;

(17) "Utilizationreview"meansareviewofthemedicalnecessityandappropriatenessof hospital resources and medical services given or proposed to be given to a covered person for purposes of determining the availability of payment. Areas of review include concurrent, prospective, and retrospective review; and

(18) "Utilization review plan" means a description of the procedures governing utilization review activities performed by an insurer or a private review agent.

304.17A-603. Application of KRS 304.17A-600 to 304.17A-633 -- Written procedures for coverage and utilization review determinations to be accessible on insurers' Web sites -- Preauthorization review requirements for insurers.

(1) KRS 304.17A-600 to 304.17A-633 shall apply to any insurer that covers citizens of the Commonwealth under a health benefit plan.

(2) An insurer shall maintain written procedures for:
(a) Determining whether a requested service, treatment, drug, or device is covered under the terms of a covered person's health benefit plan;
(b) Making utilization review determinations; and
(c) Notifying covered persons, authorized persons, and providers acting on behalf of covered persons of its determinations.

(3) An insurer shall make the written procedures required by this section readily accessible on its Web site to covered persons, authorized persons, and providers.

(4) (a) If an insurer requires preauthorization to be obtained for a service to be covered, the insurer shall maintain information on its publicly accessible Web site about the list of services and codes for which preauthorization is required. The Web site shall indicate, for each service required to be preauthorized:

1. When preauthorization was required, including the effective date or dates and the termination date or dates, if applicable;

2. The date the requirement was listed on the insurer's Web site; and

3. Where applicable, the date that preauthorization was removed.
insurer shall make the written procedures required by this section readily

(b) An insurer shall maintain a complete list of services for which preauthorization is required, including for all services where preauthorization is performed by an entity under contract with the insurer.

(c) An insurer shall not deny a claim for failure to obtain preauthorization if the preauthorization requirement was not in effect on the date of service on the claim.

(5) Except as otherwise provided in this subtitle, prior authorization shall not be required for births or the inception of neonatal intensive care services and notification shall not be required as a condition of payment.

(6) Unless otherwise specified by the provider's contract, an insurer shall not deem as incidental or deny supplies that are routinely used as part of a procedure when:

(a) An associated procedure has been preauthorized; or

(b) Preauthorization for the procedure is not required.

304.17A-605. Requirements and procedures for utilization review -- Exception for private review agent operating under contract with the federal government.

(1) KRS 304.17A-600, 304.17A-603, 304.17A-605, 304.17A-607, 304.17A-609, 304.17A-611, 304.17A-613, and 304.17A-615 set forth the requirements and procedures regarding utilization review and shall apply to:

(a) Any insurer or its private review agent that provides or performs utilization review in connection with a health benefit plan or a limited health service benefit plan; and

(b) Any private review agent that performs utilization review functions on behalf of any person providing or administering health benefit plans or limited health service benefit plans.

(2) Where an insurer or its agent provides or performs utilization review, and in all instances where internal appeals as set forth in KRS 304.17A-617 are involved, the insurer or its agent shall be responsible for:

(a) Monitoring all utilization reviews and internal appeals carried out by or on behalf of the insurer;

(b) Ensuring that all requirements of KRS 304.17A-600 to 304.17A-633 are met;

(c) Ensuring that all administrative regulations promulgated in accordance with KRS 304.17A-609, 304.17A-613, and 304.17A-629 are complied with; and

(d) Ensuring that appropriate personnel have operational responsibility for the performance of the insurer's utilization review plan.

(3) A private review agent that operates solely under contract with the federal government for utilization review or patients eligible for hospital services under Title XVIII of the Social Security Act shall not be subject to the registration requirements set forth in KRS 304.17A-607, 304.17A-609, and 304.17A-613.

304.17A-607. Duties of insurer or private review agent performing utilization reviews -- Requirement for registration -- Consequences of insurer's failure to make timely utilization review determination -- Requirement that insurer or private review agent submit changes to the department -- Requirement that private review agent provide timely notice of entities for whom it is providing review.

(1) An insurer or private review agent shall not provide or perform utilization reviews without being registered with the department. A registered insurer or private review agent shall:

(a) Have available the services of sufficient numbers of registered nurses, medical records technicians, or similarly qualified persons supported by licensed physicians with access to consultation with other appropriate physicians to carry out its utilization review activities;

(b) Ensure that, for any contract entered into on or after January 1, 2020, for the provision of utilization review services, only licensed physicians, who are of the same or similar specialty and subspecialty, when possible, as the ordering provider, shall:

1. Make a utilization review decision to deny, reduce, limit, or terminate a health care benefit or to deny, or reduce payment for a health care service because that service is not medically necessary, experimental, or investigational except in the case of a health care service rendered by a chiropractor or optometrist where the denial shall be made respectively by a chiropractor or optometrist duly licensed in Kentucky; and

2. Supervise qualified personnel conducting case reviews;

(c) Have available the services of sufficient numbers of practicing physicians in appropriate specialty areas to assure the adequate review of medical and surgical specialty and subspecialty cases;

(d) Not disclose or publish individual medical records or any other confidential medical information in the performance of utilization review activities except as provided in the Health Insurance Portability and Accountability Act, Subtitle F, secs. 261 to 264 and 45 C.F.R. secs. 160 to 164 and other applicable laws and administrative regulations;

(e) Provide a toll free telephone line for covered persons, authorized persons, and providers to contact the insurer or private review agent and be accessible to covered persons, authorized persons, and providers for forty (40) hours a week during normal business hours in this state;

(f) Where an insurer, its agent, or private review agent provides or performs utilization review, be available to conduct utilization review during normal business hours and extended hours in this state on Monday and Friday through 6:00 p.m., including federal holidays;

(g) Provide decisions to covered persons, authorized persons, and all providers on appeals of adverse determinations and coverage denials of the insurer or private review agent, in accordance with this section and administrative
regulations promulgated in accordance with KRS 304.17A-609;

(h) Except for retrospective review of an emergency admission where the covered person remains hospitalized at the time the review request is made, which shall be considered a concurrent review, or as otherwise provided in this subtitle, provide a utilization review decision in accordance with the timeframes in paragraph (i) of this subsection and 29 C.F.R. Part 2560, including written notice of the decision;

(i) 1. Render a utilization review decision concerning urgent health care services, and notify the covered person, authorized person, or provider of that decision no later than twenty-four (24) hours after obtaining all necessary information to make the utilization review decision; and

2. If the insurer or agent requires a utilization review decision of nonurgent health care services, render a utilization review decision and notify the covered person, authorized person, or provider of the decision within five (5) days of obtaining all necessary information to make the utilization review decision.
For purposes of this paragraph, "necessary information" is limited to:

a. The results of any face-to-face clinical evaluation;

b. Any second opinion that may be required; and

c. Any other information determined by the department to be necessary to making a utilization review determination;

(j) Provide written notice of review decisions to the covered person, authorized person, and providers. The written notice may be provided in an electronic format, including e-mail or facsimile, if the covered person, authorized person, or provider has agreed in advance in writing to receive the notices electronically. An insurer or agent that denies step therapy, as defined in KRS 304.17A-163, overrides or denies coverage or reduces payment for a treatment, procedure, drug that requires prior approval, or device shall include in the written notice:

1. A statement of the specific medical and scientific reasons for denial or reduction of payment or identifying that provision of the schedule of benefits or exclusions that demonstrates that coverage is not available;

2. The medical license number and the title of the reviewer making the decision;

3. Except for retrospective review, a description of alternative benefits, services, or supplies covered by the health benefit plan, if any; and

4. Instructions for initiating or complying with the insurer's internal appeal procedure, as set forth in KRS 304.17A-617, stating, at a minimum, whether the appeal shall be in writing, and any specific filing procedures, including any applicable time limitations or schedules, and the position and phone number of a contact person who can provide additional information;

(k) Afford participating physicians an opportunity to review and comment on all medical and surgical and emergency room protocols, respectively, of the insurer and afford other participating providers an opportunity to review and comment on all of the insurer's protocols that are within the provider's legally authorized scope of practice; and

(l) Comply with its own policies and procedures on file with the department or, if accredited or certified by a nationally recognized accrediting entity, comply with the utilization review standards of that accrediting entity where they are comparable and do not conflict with state law.

(2) The insurer's or private review agent's failure to make a determination and provide written notice within the time frames set forth in this section shall be deemed to be a prior authorization for the health care services or benefits subject to the review. This provision shall not apply where the failure to make the determination or provide the notice results from circumstances which are documented to be beyond the insurer's control.

(3) An insurer or private review agent shall submit a copy of any changes to its utilization review policies or procedures to the department. No change to policies and procedures shall be effective or used until after it has been filed with and approved by the commissioner.

(4) A private review agent shall provide to the department the names of the entities for which the private review agent is performing utilization review in this state. Notice shall be provided within thirty (30) days of any change.

304.17A-609. Emergency administrative regulations governing utilization review and internal appeal to be promulgated by the department.

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 which shall, at a minimum, include:

(1) A utilization review plan that contains all information utilized for conducting preadmission, admission, readmission review, preauthorization, continued stay authorization, and retrospective review and which, for each type of review, includes:

(a) Utilization review policies and procedures to evaluate proposed or delivered medical services;

(b) Time frames for review;

(c) A written summary describing the review process and required forms;

(d) Documentation that actively practicing providers with appropriate qualifications are involved in the development or adoption of utilization review criteria relating to specialty and subspecialty areas;

(e) Descriptions and names of review criteria upon which utilization review decisions are based; and

(f) Additional standards, if any, for the consideration of special circumstances;

(2) The type and qualifications of the personnel either employed or under contract to perform utilization review;

(3) Assurance that a toll-free line will be provided that covered persons, authorized persons, and providers may use to contact the insurer or private review agent;

(4) The policies and procedures to ensure that a representative of the insurer or private review agent shall be reasonably accessible to covered persons, authorized persons, and providers at least forty (40) hours per week during normal business hours;

(5) The policies and procedures to ensure that all applicable state and federal laws to protect the confidentiality of individual medical records are followed;

(6) A copy of the materials designed to inform covered persons, authorized persons, and providers of the toll-free number and the requirements of the utilization review plan;

(7) A list of the entities for which the private review agent is performing utilization review in this state; and

(8) Evidence of compliance or the ability to comply with the requirements and procedures established regarding utilization review and the administrative regulations promulgated thereunder.

(9) In lieu of disclosing information specified in subsection (1) of this section, an insurer or private review agent may submit to the department evidence of accreditation or certification, if any, with a nationally recognized accreditation organization that oversees the information described in subsections (1) to (8) of this section, provided that the department may still require the information in subsection (8) of this section or other information to demonstrate compliance with the requirements of this section and KRS 304.17A-600, 304.17A-607, 304.17A-613, 304.17A-617, 304.17A-623, and 304.17A-625 not covered by the standards of the nationally recognized accreditation organization, as well as basic information necessary for the department to contact the insurer or private review agent. Nothing in this subsection shall be construed to prohibit or in any way limit the department's authority to require the submission of information specified in subsections (1) to (8) of this section or any other information the department deems necessary for purposes of investigating a complaint that the insurer or private review agent is not in compliance with KRS 304.17A-600 to 304.17A-633.

304.17A-611. Prohibition against retrospective denial of coverage for health care services under certain circumstances.

A utilization review decision shall not retrospectively deny coverage for health care services provided to a covered person when prior approval has been obtained from the insurer or its designee for those services, unless the approval was based upon fraudulent, materially inaccurate, or misrepresented information submitted by the covered person, authorized person, or the provider.

304.17A-613. Emergency administrative regulations governing registration of insurers and private review agents seeking to conduct utilization reviews -- Procedure for handling complaints.

(1) The department shall, through the promulgation of emergency administrative regulations, develop a process:

(a) For the review of applications for registration of insurers or private review agents seeking to conduct utilization reviews;

(b) For the review of applications for insurers or private review agents seeking registration renewal to continue as a utilization review entity;

(c) Ensuring that no registration shall be approved unless the commissioner has documentation or findings that all applicants seeking registration or renewal to conduct utilization review are in compliance with the requirements and procedures established regarding utilization review, and as to renewals, have complied with KRS 304.17A-600 to 304.17A-633 and administrative regulations promulgated to enforce and to administer KRS 304.17A-600 to 304.17A-633; and

(d) Establishing fees for applications and renewals in an amount sufficient to pay the administrative costs of the program and any other costs associated with carrying out the provisions of KRS 304.17A-600, 304.17A-603, 304.17A-605, 304.17A-607, 304.17A-609, 304.17A-611, 304.17A-613, and 304.17A-615.

(2) The registration issued in accordance with this section expires on the second anniversary of the effective date unless it is renewed.

(3) The registration issued under this section is not transferable.

(4) The commissioner may revoke or suspend the utilization review registration of any insurer or private review agent who does not comply with the requirements and procedures established regarding utilization review or any administrative regulations promulgated thereunder.

(5) The department shall establish reporting requirements to:

(a) Evaluate the effectiveness of insurers and private review agents; and

(b) Determine if the utilization review plans are in compliance with the requirements and procedures established regarding utilization review and applicable administrative regulations.

(6) Upon request of any provider, authorized person, or covered person whose care is subject to review, the department shall provide copies of policies or procedures of any insurer or private review agent that has been issued a registration by the department to conduct review in this state.

(7) Notwithstanding any provision to the contrary, an insurer or private review agent registered and in good standing under the provisions of KRS 211.461 to 211.466, prior to July 14, 2000, shall be deemed in compliance with requirements and procedures established in KRS 304.17A-600 to 304.17A-633 regarding utilization review and registered accordingly.

(8) Upon receipt of written complaints from covered persons, authorized persons, or

providers stating that an insurer or a private review agent has failed to perform a review in accordance with the utilization review plan or the requirements and procedures established regarding utilization review, or administrative regulations promulgated thereunder, the commissioner shall:

(a) Send a copy of the complaint to the insurer or the private review agent within ten (10) days of receipt of the complaint, and require that any written reply be sent to the commissioner within ten (10) days; and

(b) Review the complaint and any written reply received from the insurer or private review agent within the time frames set forth in paragraph (a) of this subsection and make a recommendation to the insurer or private review agent and the covered person, authorized person, or provider.

(9) The commissioner shall consider complaints before issuing or renewing any registration or renewal of a registration to an insurer or a private review agent.

(10) Notwithstanding any provision in this section to the contrary, the department shall accept accreditation or certification by a nationally recognized accreditation organization as sufficient documentation or finding for purposes of subsections (1) and (5) of this section that the insurer or private review agent meets the application requirements for registration or renewal. Insurers or private review agents accredited or certified by a nationally recognized accreditation organization shall be deemed compliant with the utilization review and internal appeals requirements of this section and KRS 304.17A-600, 304.17A-607, 304.17A-609, 304.17A-617, 304.17A-623, and 304.17A-625 and administrative regulations to the extent the standards of such nationally recognized accreditation organization sufficiently meet these requirements. The department shall have a simplified process in administrative regulations for insurers and private review agents to register using accreditation or certification and shall limit any additional documentation only for demonstrating compliance with requirements in this section and KRS 304.17A-600, 304.17A-607, 304.17A-609, 304.17A-617, 304.17A-623, and 304.17A-625 not met by the standards of a nationally recognized accreditation organization.

304.17A-615. Prohibition against denying or reducing payments under certain circumstances.

(1) No insurer or any other person providing or administering a health benefit plan shall deny or reduce payment for a service, procedure, treatment, drug or device covered under the covered person's health benefit plan if:

(a) The covered person's provider, during normal business hours, contacts the insurer, the designee, or agent on the day the covered person is expected to be discharged, in order to request review of the covered person's continued hospitalization, and the insurer, designee, or agent fails to provide a timely utilization review decision as required by KRS 304.17A-607; or

(b) The covered person's provider makes at least three (3) documented attempts during a four (4) consecutive hour period to contact the insurer, designee, or agent, during normal business hours in order to request review of a continued hospital stay, preauthorization of treatment for a covered person who is already hospitalized, or retrospective review of an emergency hospital admission where the covered person remains hospitalized at the time the review requested is made, and the insurer, designee, or private review agent fails to be accessible as required by KRS 304.17A-607.

(2) The insurer's liability to pay for the covered person's hospitalization under the circumstances set forth in subsection (1) of this section shall extend until the insurer, designee, or private review agent issues a utilization review decision applicable to requests for review relating to matters as set forth in subsection 1(b) of this section.

(3) The insurer's liability to pay under this section shall be conditioned on:

(a) The provider establishing verifiable documentation of the contact with, and subsequent failure of the insurer, designee, or agent to make the utilization review decision as set forth in subsection (1)(a) of this section; or

(b) The provider establishing verifiable documentation of the attempt to make contact with the insurer, designee, or agent as addressed in subsection (1)(b) of this section.

(4) In either instance, the contact, or attempts to contact, as set forth in this section, shall be made by the means required by the insurer, designee, or agent for requesting utilization review.

(5) This section applies only when the request for review concerns covered health benefits and it shall not supersede any limitations or exclusions in the covered person's health benefit plan. This section shall not apply if, in requesting a review, the provider does not furnish the information requested by the insurer or agent to make a utilization review decision, or if actions by the provider impede an insurer's or private review agent's ability to issue a utilization review decision.

304.17A-617. Internal appeals process -- Procedures -- Review of coverage denials.

(1) Every insurer shall have an internal appeal process to be utilized by the insurer or its designee, consistent with this section and KRS 304.17A-619 and which shall be disclosed to covered persons in accordance with KRS 304.17A-505(1)(g). An insurer shall disclose the availability of the internal process to the covered person in the insured's timely notice of an adverse determination or notice of a coverage denial which meets the requirements set forth in KRS 304.17A-607(1)(j). For purposes of this section, "coverage denial" means an insurer's determination that a service, treatment, drug, or device is specifically limited or excluded under the covered person's health benefit plan. Where a coverage denial is involved, in addition to stating the reason for the coverage denial, the required notice shall contain instructions for filing a request for internal appeal.

(2) The internal appeals process may be initiated by the covered person, an authorized person, or a provider acting on behalf of the covered person. The internal appeals process shall include adequate and reasonable procedures for review and resolution of appeals concerning adverse determinations made under utilization review and of coverage denials, including procedures for reviewing appeals from covered persons whose medical conditions require expedited review. At a minimum, these procedures shall include the following:

(a) Insurers or their designees shall provide decisions to covered persons, authorized persons, and providers on internal appeals of adverse determinations or coverage denials within thirty (30) days of receipt of the request for internal appeal;

(b) Insurers or their designees shall render a decision not later than three (3) business days after receipt of the request for an expedited appeal of either an adverse determination or a coverage denial. An expedited appeal is deemed necessary when a covered person is hospitalized or, in the opinion of the treating provider, review under a standard time frame could, in the absence of immediate medical attention, result in any of the following:

1. Placing the health of the covered person or, with respect to a pregnant woman, the health of the covered person or the unborn child in serious jeopardy;

2. Serious impairment to bodily functions; or

3. Serious dysfunction of a bodily organ or part;

(c) Internal appeal of an adverse determination shall only be conducted by a licensed physician who did not participate in the initial review and denial. However, in the case of a review involving a medical or surgical specialty or subspecialty, the insurer or agent shall, upon request by a covered person, authorized person, or provider, utilize a board eligible or certified physician in the appropriate specialty or subspecialty area to conduct the internal appeal;

(d) Those portions of the medical record that are relevant to the internal appeal, if authorized by the covered person and in accordance with state or federal law, shall be considered and providers given the opportunity to present additional
information; and

(e) In addition to any previous notice required under KRS 304.17A-607(1)(j), and to facilitate expeditious handling of a request for external review of an adverse determination or a coverage denial, an insurer or agent that denies, limits, reduces, or terminates coverage for a treatment, procedure, drug, or device for a covered person shall provide the covered person, authorized person, or provider acting on behalf of the covered person with an internal appeal determination letter that shall include:

1. A statement of the specific medical and scientific reasons for denying coverage or identifying that provision of the schedule of benefits or exclusions that demonstrates that coverage is not available;

2. The state of licensure, medical license number, and the title of the person making the decision;

3. Except for retrospective review, a description of alternative benefits, services, or supplies covered by the health benefit plan, if any; and

4. Instructions for initiating an external review of an adverse determination, or filing a request for review with the department if a coverage denial is upheld by the insurer on internal appeal.

(3) The department shall establish and maintain a system for receiving and reviewing requests for review of coverage denials from covered persons, authorized persons, and providers. For purposes of this subsection,

"coverage denials" shall not include an adverse determination as defined in KRS 304.17A-600 or subsequent denials arising from an adverse determination.

(a) On receipt of a written request for review of a coverage denial from a covered person, authorized person, or provider, the department shall notify the insurer which issued the denial of the request for review and shall call for the insurer to respond to the department regarding the request for review within ten (10) business days of receipt of notice to the insurer.

(b) Within ten (10) business days of receiving the notice of the request for review from the department, the insurer shall provide to the department the following information:

1. Confirmation as to whether the person who received or sought the health service for which coverage was denied was a covered person under a health benefit plan issued by the insurer on the date the service was sought or denied;

2. Confirmation as to whether the covered person, authorized person, or provider has exhausted his or her rights under the insurer's appeal process under this section; and

3. The reason for the coverage denial, including the specific limitation or exclusion of the health benefit plan demonstrating that coverage is not available.

(c) In addition to the information described in paragraph (b) of this subsection, the insurer and the covered person, authorized person, or provider shall provide to the department any information requested by the department that is germane to its review.

(d) On the receipt of the information described in paragraphs (b) and (c) of this subsection, unless the department is not able to do so because making a determination requires resolution of a medical issue, it shall determine whether the service, treatment, drug, or device is specifically limited or excluded under the terms of the covered person's health benefit plan. If the department determines that the treatment, service, drug, or device is not specifically limited or excluded, it shall so notify the insurer, and the insurer shall either cover the service, or afford the covered person an opportunity for external review under KRS 304.17A-621, 304.17A-623, and 304.17A-625, where the conditions precedent to the review are present. If the department notifies the insurer that the treatment, service, drug, or device is specifically limited or excluded in the health benefit plan, the insurer is not required to cover the service or afford the covered person an external review.

(e) An insurer shall be required to cover the treatment, service, drug, or device that was denied or provide notification of the right to external review in accordance with paragraph (d) of this subsection whether the covered person has disenrolled or remains enrolled with the insurer.

(f) If the covered person has disenrolled with the insurer, the insurer shall only be required to provide the treatment, service, drug, or device that was denied for a period not to exceed thirty (30) days, or provide the covered person the opportunity for external review.

304.17A-619. Duty of covered person, authorized person, or provider to provide insurer with new information regarding internal appeal -- Time frame for insurer to render a decision based on new information -- Insurer's failure to make timely determination or provide written notice.

(1) If the covered person, authorized person, or provider has new clinical information regarding the covered person's internal appeal he or she shall provide that information to the insurer prior to the initiation of the external review process. The insurer shall have five (5) business days from the date of the receipt of the information to render a decision based on the new information. If new information is provided in accordance with this section, the sixty (60) day time frame for commencing an external review as set forth in KRS 304.17A-623(4), shall not begin to run, until the insurer or its designee renders a decision regarding the new information.

(2) The insurer's failure to make a determination or provide a written notice within the time frames set forth in KRS 304.17A-617 shall be deemed to be an adverse determination by the insurer for the purpose of initiating an external review as set forth in KRS 304.17A-623.

304.17A-621. Independent External Review Program established.

The Independent External Review Program is hereby established in the department. The program shall provide covered persons with a formal, independent review to address disagreements between the covered person and the covered person's insurer regarding an adverse determination made by the insurer, its designee, or a private review agent. This section and KRS 304.17A-623 and 304.17A-625 establish requirements and procedures governing external review and independent review entities.

304.17A-623. External review of adverse determination -- Who may request -- Criteria for review -- Fee -- Conditions under which covered person not entitled to review -- Resolution of disputes -- Confidentiality -- Expedited external review.

(1) Every insurer shall have an external review process to be utilized by the insurer or its designee, consistent with this section and which shall be disclosed to covered persons in accordance with KRS 304.17A-505(1)(g). An insurer, its designee, or agent shall disclose the availability of the external review process to the covered person in the insured's timely notice of an adverse determination or notice of a coverage denial as set forth in KRS 304.17A-607(1)(j) and in the denial letter required in KRS 304.17A-617(1) and (2)(e). For purposes of this section "coverage denial" means an insurer's determination that a service, treatment, drug, or device is specifically limited or excluded under the covered person's health benefit plan.

(2) A covered person, an authorized person, or a provider acting on behalf of and with the consent of the covered person, may request an external review of an adverse determination rendered by an insurer, its designee, or agent.

(3) The insurer shall provide for an external review of an adverse determination if the following criteria are met:

(a) The insurer, its designee, or agent has rendered an adverse determination;

(b) The covered person has completed the insurer's internal appeal process, or the insurer has failed to make a timely determination or notification as set forth in KRS 304.17A-619(2). The insurer and the covered person may however, jointly agree to waive the internal appeal requirement;

(c) The covered person was enrolled in the health benefit plan on the date of service or, if a prospective denial, the covered person was enrolled and eligible to receive covered benefits under the health benefit plan on the date the proposed service was requested; and

(d) The entire course of treatment or service will cost the covered person at least one hundred dollars ($100) if the covered person had no insurance.

(4) The covered person, an authorized person, or a provider with consent of the covered person shall submit a request for external review to the insurer within sixty (60) days, except as set forth in KRS 304.17A-619(1), of receiving notice that an adverse determination has been timely rendered under the insurer's internal appeal process. As part of the request, the covered person shall provide to the insurer or its designee written consent authorizing the independent review entity to obtain all necessary medical records from both the insurer and any provider utilized for review purposes regarding the decision to deny, limit, reduce or terminate coverage.

(5) The covered person shall be assessed a one (1) time filing fee of twenty-five dollars ($25) to be paid to the independent review entity and which may be waived if the independent review entity determines that the fee creates a financial hardship on the covered person. The fee shall be refunded if the independent review entity finds in favor of the covered person.

(6) A covered person shall not be afforded an external review of an adverse determination if:

(a) The subject of the covered person's adverse determination has previously gone through the external review process and the independent review entity found in favor of the insurer; and

(b) No relevant new clinical information has been submitted to the insurer since the independent review entity found in favor of the insurer.

(7) The department shall establish a system for each insurer to be assigned an independent review entity for external reviews. The system established by the department shall be prospective and shall require insurers to utilize independent review entities on a rotating basis so that an insurer does not have the same independent review entity for two (2) consecutive external reviews. The department shall contract with no less than two (2) independent review entities.

(8) (a)
If a dispute arises between an insurer and a covered person regarding the covered person's right to an external review, the covered person may file a complaint with the department. Within five (5) days of receipt of the complaint, the department shall render a decision and may direct the insurer to submit the dispute to an independent review entity for an external review if it finds:

1. The dispute involves denial of coverage based on medical necessity or the service being experimental or investigational; and

2. All of the requirements of subsection (3) of this section have been met.

(b) The complaint process established in this section shall be separate and distinct from, and shall in no way limit other grievance or complaint processes available to consumers under other provisions of the KRS or duly promulgated administrative regulations. This complaint process shall not limit, alter, or supplant the mechanisms for appealing coverage denials established in KRS 304.17A-617.

(9) The external review process shall be confidential and shall not be subject to KRS 61.805 to 61.850 and KRS 61.870 to 61.884.

(10) External reviews shall be conducted in an expedited manner by the independent review entity if the covered person is hospitalized, or if, in the opinion of the treating provider, review under the standard time frame could, in the absence of immediate medical attention, result in any of the following:

(a) Placing the health of the covered person or, with respect to a pregnant woman, the health of the covered person or her unborn child in serious jeopardy;

(b) Serious impairment to bodily functions; or

(c) Serious dysfunction of a bodily organ or part.

(11) Requests for expedited external review, shall be forwarded by the insurer to the independent review entity within twenty-four (24) hours of receipt by the insurer.

(12) For expedited external review, a determination shall be made by the independent review entity within twenty-four (24) hours from the receipt of all information required from the insurer. An extension of up to twenty-four (24) hours may be allowed if the covered person and the insurer or its designee agree. The insurer or its designee shall provide notice to the independent review entity and to the covered person, by same-day communication, that the adverse determination has been assigned to an independent review entity for expedited review.

(13) External reviews which are not expedited shall be conducted by the independent review entity and a determination made within twenty-one (21) calendar days from the receipt of all information required from the insurer. An extension of up to fourteen (14) calendar days may be allowed if the covered person and the insurer are in agreement.

304.17A-625. Factors to be considered by independent review entity conducting external review -- Basis for decision -- Insurer's responsibilities -- Contents, admissibility, and effect of decision -- Consequence of insurer's failure to provide coverage -- Liability -- Written complaints.

(1) In making its decision, an independent review entity conducting the external review shall take into account all of the following:

(a) Information submitted by the insurer, the covered person, the authorized person, and the covered person's provider, including the following:

1. The covered person's medical records;

2. The standards, criteria, and clinical rationale used by the insurer to make its decision; and

3. The insurer's health benefit plan;

(b) Findings, studies, research, and other relevant documents of government agencies and nationally recognized organizations, including the National Institutes of Health, or any board recognized by the National Institutes of Health, the National Cancer Institute, the National Academy of Sciences, and the United States Food and Drug Administration, the Centers for Medicare & Medicaid Services of the United States Department of Health and Human Services, and the Agency for Health Care Research and Quality; and

(c) Relevant findings in peer-reviewed medical or scientific literature, published opinions of nationally recognized medical specialists, and clinical guidelines adopted by relevant national medical societies.

(2) The independent review entity shall base its decision on the information submitted under subsection (1) of this section. In making its decision, the independent review entity shall consider safety, appropriateness, and cost effectiveness.

(3) The insurer shall provide any coverage determined by the independent review entity to be medically necessary. The independent review entity shall not be permitted to allow coverage for services specifically limited or excluded by the insurer in its health benefit plan. The decision shall apply only to the individual covered person's external review.

(4) Nothing in this section shall be construed as requiring an insurer to provide coverage for out of network services, procedures, or tests, except as set forth in KRS 304.17A-515(1)(c) and 304.17A-550.

(5) The insurer shall be responsible for the cost of the external review.

(6) The independent review entity shall provide to the covered person, treating provider, insurer, and the department a decision which shall include:

(a) The findings for either the insurer or covered person regarding each issue under review;

(b) The proposed service, treatment, drug, device, or supply for which the review was performed;

(c) The relevant provisions in the insurer's health benefit plan and how applied; and

(d) The relevant provisions of any nationally recognized and peer-reviewed medical or scientific documents used in the external review.

(7) The decision of the independent review entity shall not be made solely for the convenience of the insurer, the covered person, or the provider.

(8) Consistent with the rules of evidence, a written decision prepared by an independent review entity shall be admissible in any civil action related to the adverse determination. The independent review entity's decision shall be presumed to be a scientifically valid and accurate description of the state of medical knowledge at the time it was written.

(9) The decision of the independent review entity shall be binding on the insurer with respect to that covered person. Failure of the insurer to provide coverage as required by the independent review entity shall:

(a) Be a violation of the insurance code of a nature sufficient to warrant the commissioner revoking or suspending the insurer's license or certificate of authority; and

(b) Constitute an unfair claims settlement practice as set forth in KRS 304.12- 230.

(10) Failure to provide coverage as required by the independent review entity shall also subject the insurer to the provisions of KRS 304.99-010 and 304.99-020 and require the insurer to pay the claim that was the subject of the external review, without need for the covered person or authorized person to further establish a right as to the payment amount. Reasonable attorney fees associated with the actions of the insured necessary to collect amounts owed the covered person shall be assessed against and borne by the insurer.

(11) The insurer shall implement the decision of the independent review entity whether the covered person has disenrolled or remains enrolled with the insurer.

(12) If the covered person has been disenrolled with the insurer, the insurer shall only be required to provide the treatment, service, drug, or device that was previously denied by the insurer, its agent, or designee and later approved by the independent review entity for a period not to exceed thirty (30) days.

(13) Within thirty (30) days of the decision in favor of the covered person by the independent review entity, the insurer shall provide written notification to the department that the decision has been implemented in accordance with this section.

(14) An independent review entity and any medical specialist the entity utilizes in conducting an external review shall not be liable in damages in a civil action for injury, death, or loss to person or property and is not subject to professional disciplinary action for making, in good faith, any finding, conclusion, or determination required to complete the external review. This subsection does not grant immunity from civil liability or

professional disciplinary action to an independent review entity or medical specialist for an action that is outside the scope of authority granted in KRS 304.17A-621, 304.17A-623, and 304.17A-625.

(15) Nothing in KRS 304.17A-600 to 304.17A-633 shall be construed to create a cause of action against any of the following:

(a) An employer that provides health care benefits to employees through a health benefit plan;

(b) A medical expert, private review agent, or independent review entity that participates in the utilization review, internal appeal, or external review addressed in KRS 304.17A-600 to 304.17A-633; or

(c) An insurer or provider acting in good faith and in accordance with any finding, conclusion, or determination of an Independent Review Entity acting within the scope of authority set forth in KRS 304.17A-621, 304.17A-623, and 304.17A-625.

(16) The covered person, insurer, or provider in the external review may submit written complaints to the department regarding any independent review entity's actions believed to be an inappropriate application of the requirements set forth in KRS 304.17A-621, 304.17A-623, and 304.17A-625. The department shall promptly review the complaint, and if the department determines that the actions of the independent review entity were inappropriate, the department shall take corrective measures, including decertification or suspension of the independent review entity from further participation in external reviews. The department's actions shall be subject to the powers and administrative procedures set forth in Subtitle 17A of KRS Chapter 304.

304.17A-627. Certification as independent review entity -- Requirements and restrictions.

(1) To be certified as an independent review entity under this chapter, an organization shall submit to the department an application on a form required by the department. The application shall include the following:

(a) The name of each stockholder or owner of more than five percent (5%) of any stock or options for an applicant;

(b) The name of any holder of bonds or notes of the applicant that exceeds one hundred thousand dollars ($100,000);

(c) The name and type of business of each corporation or other organization that the applicant controls or with which it is affiliated and the nature and extent of the affiliation or control;

(d) The name and a biographical sketch of each director, officer, and executive of the applicant and any entity listed under paragraph (c) of this subsection and a description of any relationship the named individual has with an insurer as defined in KRS 304.17A-600 or a provider of health care services;

(e) The percentage of the applicant's revenues that are anticipated to be derived from independent reviews;

(f) A description of the minimum qualifications employed by the independent review entity to select health care professionals to perform external review, their areas of expertise, and the medical credentials of the health care professionals currently available to perform external reviews; and
(g) The procedures to be used by the independent review entity in making review determinations.

(2) If at any time there is a material change in the information included in the application, provided for in subsection (1) of this section, the independent review entity shall submit updated information to the department.

(3) An independent review entity shall not be a subsidiary of, or in any way affiliated with, or owned, or controlled by an insurer or a trade or professional association of payors.

(4) An independent review entity shall not be a subsidiary of, or in any way affiliated with, or owned, or controlled by a trade or professional association of providers.

(5) Health care professionals who are acting as reviewers for the independent review entity shall hold in good standing a nonrestricted license in a state of the United States.

(6) Health care professionals who are acting as reviewers for the independent review entity shall hold a current certification by a recognized American medical specialty board or other recognized health care professional boards in the area appropriate to the subject of the review, be a specialist in the treatment of the covered person's medical condition under review, and have actual clinical experience in that medical condition.

(7) The independent review entity shall have a quality assurance mechanism to ensure
the timeliness and quality of the review, the qualifications and independence of the physician reviewer, and the confidentiality of medical records and review material.

(8) Neither the independent review entity nor any reviewers of the entity, shall have any material, professional, familial, or financial conflict of interest with any of the following:

(a) The insurer involved in the review;

(b) Any officer, director, or management employee of the insurer;

(c) The provider proposing the service or treatment or any associated independent practice association;

(d) The institution at which the service or treatment would be provided;

(e) The development or manufacture of the principal drug, device, procedure, or other therapy proposed for the covered person whose treatment is under review; or

(f) The covered person.

(9) As used in this section, "conflict of interest" shall not be interpreted to include:

(a) A contract under which an academic medical center or other similar medical center provides health care services to covered persons, except for academic medical centers that may provide the service under review;

(b) Provider affiliations which are limited to staff privileges; or

(c) A specialist reviewer's relationship with an insurer as a contracting health care provider, except for a specialist reviewer proposing to provide the service under review.

(10) On an annual basis, the independent review entity shall report to the department the following information:

(a) The number of independent review decisions in favor of covered persons;

(b) The number of independent review decisions in favor of insurers;

(c) The average turnaround time for an independent review decision;

(d) The number of cases in which the independent review entity did not reach a decision in the time specified in statute or administrative regulation; and

(e) The reasons for any delay.

304.17A-629. Administrative regulations to implement provisions of KRS 304.17A- 621, 304.17A-623, 304.17A-625, 304.17A-627, 304.17A-629, and 304.17A-631.

The commissioner shall promulgate administrative regulations to implement the provisions of KRS 304.17A-621, 304.17A-623, 304.17A-625, 304.17A-627, 304.17A- 629, and 304.17A-631.

304.17A-631. Time for insurers to comply with administrative regulations.

Insurers subject to the administrative regulations required under KRS 304.17A-629 shall have no less than ninety (90) days to comply with the provisions of the administrative regulations.

304.17A-633. Commissioner to report to Interim Joint Committee on Banking and Insurance and to Governor -- Contents of report.

The commissioner shall report every six (6) months to the Interim Joint Committee on Banking and Insurance, and to the Governor on the state of the Independent External Review Program. The report shall include a summary of the number of reviews conducted, medical specialties affected, and a summary of the findings and recommendations made by the independent external review entity.