Kentucky Department of Insurance
IRE Certification Review Guide

Date of Receipt:_____ **Expiration Date:** _____

ENTITY NAME:_____

Entity ID #_____

Accreditation Status: ☐ **Accredited:** ☐ **URAC** ☐ **NCQA** ☐ **Other** ☐ **Not Accredited**

URAC Health UM Accreditation Version _____ **(If accredited, please attach a copy of the accreditation certificate)**

		Comments
Appropriate fee received ($500 new/renewal)		
Proof of registration with Secretary of State		

Review dates/times:

Date of Certification: _____ **Reviewer Signature:** _____

Application	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-627(1)		
Submit the following information:		
(a) Name of each stockholder or owner of more than 5% of any stock or options		
(b) Name of any holder of bonds or notes which exceed $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) Biographical sketch of each director, officer, and executive, and any entity listed under paragraph (c), and a description of any relationship the named individual has with an insurer or a provider of health care services		
(e) The percentage of revenues that are anticipated to be derived from independent reviews		

Accessibility	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3(13)		
Provide toll-free telephone access that:		
(a) Operates at a minimum from 9:00 am to 5:00 pm each business day in each time zone where the services under review are in dispute (Eastern and Central)		
(b) Allows for receiving after-hours requests for external review		
(c) Allows for acting on expedited external review requests		

Medical Director	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3(7)		
The IRE is required to have a Medical Director or clinical director with professional post-residency experience in direct patient care who is required to:		
(a) Hold a current license to practice medicine in a state in the United States		
(b) Provide guidance for the medical aspects of the external review process		
(c) Oversee the medical aspects of the quality management program		
(d) Oversee the medical aspects of the reviewer credentialing program		

Reviewers	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3(6)(c)		
Adequacy & Appropriateness – The IRE must establish criteria for:		
(a) Selection of a qualified reviewer, including the initial verification and re-verification of credentials every 3 years		
(b) Ensuring that an appropriate reviewer performs the external review		
(c) Ensuring that an appropriate number of reviewers is used for each external review		
(d) Ensuring that at least one reviewer qualified in each medical specialty and subspecialty, per the American Board of Medical Specialists, is available for external reviews		
KRS 304.17A-627(6) and (7), 806 KAR 17:290, Section 3(5)		
Reviewers are required to:		
(a) Hold in good standing an active unrestricted license in a state of the United States		
(b) Hold a current board certification by a recognized American medical specialty board (American Board of Medical Specialties, American Osteopathic Association, or American Board of Podiatric Surgery) or other recognized health care professional board in the area appropriate to the subject of the review		
(c) Have recent experience or familiarity with current body of knowledge and applicable specialty practice		
(d) Have at least 5 years' experience in the specialty of the external review		
(e) Be a specialist in the treatment of the covered person's medical condition under review, and have actual clinical experience in the medical condition		
(f) Be able to conduct an external review of a coverage denial which requires resolution of a medical issue, and of an adverse determination		
806 KAR 17:290, Section 3(5)(a)		
Health Insurance & Benefit Specialist – The IRE must have a reviewer with expertise in health insurance benefits and contracts, who is available to serve as a reviewer, in addition to a health care professional reviewer, in an external review of a coverage denial which requires the resolution of a medical issue.		

KRS 304.17A-627(9) and 806 KAR 17:290, Section 3(20)		
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 contracting health care 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		
(c) A specialist reviewer's relationship with an insurer as a contracting health care provider, except for the specialist reviewer proposing to provide the service under review.		
Use of Multiple Reviewers – If more than one reviewer is utilized in making a decision:		
(a) Render an overall decision based upon the majority decision of the reviewers; or		
(b) If the reviewers are evenly split as to the decision, request an additional reviewer to make a binding majority decision		
Note: Insurers are not prohibited from requesting the IRE's use of specialties/subspecialties or that the IRE use multiple reviewers. DOI's position is that the IRE is not required to grant these requests unless the IRE agrees that they are warranted.		

Organizational Conflict of Interest	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-627(4) and (5)		
The IRE shall not be a subsidiary of, or in any way affiliated with, or owned, or controlled by:		
(a) An insurer or trade or professional association of payers		
(b) A trade or professional association of providers		
KRS 304.17A-627(9)		
The IRE shall not 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 services or treatment or any associated independent practice		
(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		
(f) The covered person		

Confidentiality and Consents	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-623(9) and 806 KAR 17:290, Section 3(11)		
The external review process shall be confidential, and the IRE must have policies and procedures for the maintenance and confidential treatment of external review records.		
The IRE may obtain all necessary medical records from both the insurer and any provider utilized for review purposes if the covered person provides the insurer or its designee written consent.		

Handling a request for assignment	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3		
Insurers are required to contact the choses IRE by telephone prior to sending any file materials.		
Upon request for an assignment, the IRE must immediately determine whether a conflict of interest exists, that confidentiality requirements of the insurer can be met, and that an appropriate reviewer is available, and immediately provide notification to the insurer and DOI of the rejection of the assignment.		
The rejection notification provided to the Department must include:		
(a) If a conflict of interest exists		
(b) Confidentiality requirements of an insurer cannot be met		
(c) Due to circumstances beyond the IRE's control, an appropriate reviewer becomes unavailable		
(d) If no conflict of interest or confidentiality concerns exists, provide written notice of acceptance to the insurer and **the DOI** within 24 hours of receipt of request		

Decision Criteria	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-625		
The IRE shall base its decision on the information submitted, and shall consider safety, appropriateness and cost effectiveness.		
The decision shall not be made solely for the convenience of the insurer, the covered person, or the provider.		
The decision shall take into account the following and not base the decision only on information provided by the insurer:		
(a) Information submitted by the insurer		
(b) Findings, studies, research, and other relevant documents of government agencies and nationally recognized organizations		
(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.		
Preemption: If an IRE receives information within the five-day timeframe of the initial assignment of the external review the information shall be considered in the review and shall be forwarded to the insurer within one business day of receipt of the IRE.		

Decision Criteria (continued)	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-625(1) and 806 KAR 17:290, Section 2		
For each external review, insurers are required to provide the IRE with the following:		
(a) The covered person's medical records		
(b) The standards, criteria and clinical rationale used by the insurer to make its decision		
(c) A complete copy of the covered person's health benefit plan		
(d) A copy of the medical records release form		
(e) The completed form "External Review Information Face Sheet (HIPMC-IRE-6 10/2022)"		
(f) If the case involves a coverage denial that requires resolution of a medical issue, a copy of the determination letter issued by DOI.		

Decision Timeframes	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-623(12),(13)		
For **expedited** external reviews, a determination shall be made with in 24 hours of receipt of all information required from the insurer.		
For **non-expedited** external reviews, a determination shall be made within 21 calendar days from receipt of all information required from the insurer.		

Time Extensions	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3		
One-time extensions of the required timeframes are allowed; the IRE should establish criteria for determining when an extension is needed. Prior to taking an extension, the IRE is required to obtain permission from both the insurer and the covered person:		
(a) 24 hours for expedited reviews – Preemption in no event shall the time period exceed 72 hours from the receipt of the request by the insurer		
(b) 14 calendar days for non-expedited reviews – Preemption in no event shall the time period exceed 45 days from the receipt of the request by the insurer		

Decision Notification Letter Contents	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-623 and 806 KAR 17:290, Section 3		
The IRE is required to provide written notification of an external review decision to the covered person, authorized person, treating provider, and insurer within 2 business days of making the decision. The letter must include the following:		
(a) The date the decision was rendered		
(b) The title, license number, state of licensure, and specialty certification, if any, of the reviewer		
(c) The name and telephone number of a contact person who may provide additional information relating to the review		
(d) The findings regarding each issue under review		
(e) The proposed service, treatment, drug, device, or supply for which the review was performed		
(f) The relevant provisions in the insurer's health plan and how applied		
(g) The relevant provisions of any nationally recognized and peer-reviewed medical or scientific documents used in the external review (if no literature cites are referenced, the letter must note this, and explain why none are referenced)		
(h) A statement that the decision is final and binding upon the insurer and the covered person and that any comments, questions, or complaints shall be submitted in writing to the DOI.		
The IRE shall not 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.		

Fee Requirements – Covered Person	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-623(5) and 806 KAR 17:290, Section 5		
The filing fee shall be waived if the IRE determines that it creates a financial hardship. The criteria for waiving the fee are:		
(a) Gross income of the covered person is below 200% of the Federal poverty level based on family size as shown by a Federal income tax return for the previous year or		
(b) The covered person is a participant in one of the following: National Prescription Drug Patient Assistance, Kentucky Transitional Assistance, Medicaid, or unemployment insurance. *Preemption provisions still apply but a $75 annual limit applies for each covered person for a single plan year.*		

Fee Requirements – Review	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3		
Establish a fee structure, to be available upon request, for each type or level of external review, including fees for:		
(a) A completed adverse determination		
(b) A completed coverage denial which requires resolution of a medical issue		
(c) An incomplete external review due to reversal of an internal appeal decision		
806 KAR 17:290, Section 5		
The total fee charged for an external review shall not exceed $800 unless justification for a higher fee in the case of unusual or complicated circumstances is submitted to DOI for approval prior to billing the insurer. HIPMC-IRE-5 09/2020		

Quality Assurance	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3(15)		
The IRE is required to establish and maintain a written quality assurance program, to be made available to the public upon request, which addresses:		
(a) Scope and objectives		
(b) Program organization		
(c) Monitoring and oversight mechanism		
(d) Evaluation and organizational improvement of external review activities, including		
a. Objectives and approaches used in the monitoring and evaluation of external review activities, including the systematic evaluation of complaints for patterns and trends		
b. The implementation of an action plan to improve or correct an identified problem		
c. The procedures to communicate the results of an action plan to its employees		

Records Retention	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 3(12)		
The IRE is required to maintain written records of external reviews for a minimum of 5 years, including the following, as applicable:		
(a) All documentation relating to the external review		
(b) The IRE's decision regarding each issue identified in the external review		
(c) The name, credentials, and specialty of the reviewer		
(d) Medical evidence and information considered during the review		
(e) Reference to any medical literature, research data, or national clinical criteria upon which the decision is based		
(f) A copy of the relevant policy language of the insurer, including any relevant contractual definition of medical necessity		
(g) A copy of the adverse determination or coverage denial which required resolution of a medical issue, and the internal appeal decision		
(h) A copy of all correspondence and communication between the IRE, the reviewer, and any other person regarding the external review, including a copy of the final decision letter.		

Immediate Termination of an External Review	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290(3)(19)		
IREs are required to notify DOI by phone followed up with written notification (email) and if applicable the insurer of the assignment in event the following occurs:		
Should an IRE or reviewer become unavailable for reasons beyond the control of the IRE including acts of God, natural disasters, epidemics, strikes or other labor disruptions, war, civil disturbance, riots or complete or partial disruption of the facilities.		

Complaints	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 8		
If DOI receives a complaint about an IRE, a copy of the complaint letter will be forwarded to the IRE. The IRE is required to respond in writing within 10 business days of receipt of the letter; the response must include the following:		
(a) Any information relating to the complaint		
(b) Corrective actions to resolve the complaint, if any, including timeframes for those actions		
(c) A mechanism to evaluate any corrective actions		

Annual Reporting Requirements	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 10		
IREs are required to submit the following annual report by March 31st of each year for the previous calendar year		
• Annual IRE Report, HIPMC-IRE-4 (10/2022)		

Reporting Changes	*Bookmark Name*	*Policy or Procedure page #*
KRS 304.17A-627(3) and 806 KAR 17:290, Section 3 and Section 5		
Submit a copy of any material change(s) to information provided on the application, in writing. Changes are effective on approval by the Commissioner. Any change must be accompanied by a $50 filing fee made payable to the Kentucky State Treasurer along with a copy of the Independent Review Entity Application for Certification Face Sheet (page 3 of the HIPMC-IRE-1 (10/2022) form) Submit a copy of any changes to address or contact within 30 days of the change to the DOI, pursuant to KRS 304.2-120(4).		

Ceasing Operations	*Bookmark Name*	*Policy or Procedure page #*
806 KAR 17:290, Section 11(1)(b)		
If an IRE decides to cease operations, DOI must be notified immediately in writing that the IRE intends to cease accepting new assignments		
The IRE is required to submit to the DOI, within 30 days of the planned cessation date, or as soon as practicable, the following:		
(a) Written notice of cessation of operations, including the date of cessation and the number of pending external reviews with corresponding assignment dates		
(b) A written action plan for ceasing operations, to include the projected date of rendering decision for each review which has not been acted upon, and the projected date of submission of the annual report		
(c) The action plan is subject to DOI approval, and upon approval, the IRE is required to send written notification to insurers of the date of cessation		
(d) The IRE is not required to provide a 30-day advance notice of termination of participation in the Kentucky IRE Program, if the termination is "for reasons beyond the IRE's control". NOTE: DOI will provide the IRE with a list of contact for insurers.		