Kentucky Department of Insurance
Application for Certification of an Independent Review Entity

Instructions for submitting application. Following is an application form that shall be used to make application for certification as an Independent Review Entity (IRE) to conduct external reviews of disputes between covered persons and health benefit plans in Kentucky. An Applicant shall complete all applicable sections of the application and provide all necessary documentation as evidence of compliance with KRS 304.17A-621 through 304.17A-631, and 806 KAR 17: 290, as applicable. In submitting the documentation, it is requested that the Applicant label any formal Policy and Procedure, as such, ensuring that it indicates the name of the Applicant's organization and most recent revision date. The completed application and supporting documentation should be submitted in a Portable Document Format (PDF) document bookmarked to correspond to each of the requirements outlined in this application and should be forwarded via email to DOI.UtilizationReview@ky.gov. The appropriate filing fee indicated on page 2 made payable to the Kentucky State Treasurer must be submitted along with a copy of page 2 of this application to: Kentucky Department of Insurance, Division of Health, Life Insurance and Managed Care, Utilization Review Registration and Appeals Branch, 500 Mero Street, 2 SE 11, P.O. Box 517, Frankfort, KY 40602

Instructions for submitting changes to an approved Independent Review Entity application. The application of an independent review entity certified in Kentucky and any supporting documentation shall be maintained on file in the Department of Insurance. If at any time there is a change in the information included in the application information, including, but not limited to ownership or control of the independent review entity, the Department of Insurance shall be notified in accordance with KRS 304.17A-627(2) and 806 KAR 17:290. A filing fee of fifty dollars ($50) made payable to the Kentucky State Treasurer shall be submitted with a change of application information to the address indicated above.

In order for the Department to review and approve or deny any changes to an application, it is requested that the changes be reported in the following manner.

1. Complete the face sheet, which is Page 2 of the Independent Review Entity Application for Certification in its entirety.

2. Report the changes by following these steps:
   a. Identify and report the specific section and item of the application that is being changed (e.g., Section A: Corporate Profile, Item 14);
   b. Report the most current language in the application information and proposed change (e.g., Current language: "8:00 a.m. to 4:30 p.m. EST", Proposed language: "7:30 a.m. to 5:00 p.m. EST")
   c. Report the rationale for the change (e.g., Hours of operation changed to promote efficiency in operations);
   d. Or, provide a redlined version of the policy and procedure showing all revisions, deletions, additional language, etc.; and
   e. Provide a final version of the policy and procedure incorporating the changes.

3. Identify the proposed date of implementation of the change, if applicable.

4. Include an attestation on company letterhead that is signed and dated by the appropriate officer(s) of the organization and/or legal counsel. The attestation should include that the information and material submitted is true and accurate and the applicable statutory and regulatory requirements were considered prior to proposing the change.

Any questions relating to this information, the application or process for certification of an independent review entity may be directed to staff of the Utilization Review Registration and Appeals Branch at 502-564-6088.

Kentucky Department of Insurance
Division of Health, Life Insurance and Managed Care
Independent Review Entity Application for Certification Face Sheet

Company Name	Phone No. (800# if available)	
DBA Name	Primary Contact Person	Fed. Tax ID. No.
Business Address	Business Address	
Fax Number	E-Mail Address	

Check Appropriate Box and **Make Check Payable to Kentucky State Treasurer**

- ☐ Application for Certification of an Independent Review Entity - Filing fee of $500.00
- ☐ Application for Renewal of Certification of an Independent Review Entity - Filing fee of $500.00
- ☐ Changes to previously approved Independent Review Entity Application - Filing fee of $50.00

A FILING CANNOT BE ACCEPTED UNLESS ACCOMPANIED BY THE APPROPRIATE FEE

Certificate of Person Responsible for filing

I certify that I have been authorized by the board of directors or management committee of the company or organization listed above to make this filing.

Name (Signature Required)	Position	Date

Name (Print or type)

For Department of Insurance Administrative Services Staff Only
(External Appeals)

Date: _____ Amount: _____ Check No.: _____ Initials: _____

CERTIFICATION or RENEWAL OF CERTIFICATION

(Must be completed by <u>all</u> Applicants. Indicate not applicable (N/A) and explain why not applicable, where appropriate)

Primary Contact Person for this Application

Primary Contact Person & Title _____

Mailing Address _____
Street

_____
City/State/Zip Code

Phone Number _____

Fax Number _____

E-Mail Address _____

SECTION A: CORPORATE PROFILE

(Must be completed by <u>all</u> Applicants. Indicate not applicable (N/A) and explain why not applicable, where appropriate)

1. Please list name, title, phone number, and e-mail address for the following positions:

Chief Executive Officer _____
Name

_____
Title

_____
Telephone

_____
Electronic Mail Address

_____
Address

Corporate Medical/Clinical Director _____
Name

_____
Title/State of Licensure/License #

_____
Telephone

_____
Electronic Mail Address

_____
Address

SECTION A: CORPORATE PROFILE (continued)

Please complete or respond as follows (additional pages may be added for responses). Bookmark each of the items below according to the item number, if providing a document, policy, or procedure as documentation of compliance.

1. Type of Entity (check all that apply)

☐ Corporation ☐ Partner ☐ Association ☐ Limited Liability Co.

☐ For-profit ☐ Not-for-Profit ☐ Public ☐ Private

☐ Mutual ☐ Stock _____ ☐ Other (Please specify) _____

2. Date of Incorporation or formation as legal entity _____

3. State of Incorporation _____

4. Attach a copy of the Applicant's Articles of Incorporation or documentation of organization as a legal entity. For parts of the business that were purchased after formation of the founding organization, please describe the type of business relationship that exists between the corporate and the added business entity (e.g., amended articles of incorporation, signed meeting minutes describing relationship with new entity, letter signed by both entities stating relationship).

5. Are any of the following changes anticipated in any of the following during the next year? (check all that apply)

Merger or consolidation:	☐ YES	☐ NO
Change in control and or ownership:	☐ YES	☐ NO

Material changes* in:		
Organization	☐ YES	☐ NO
Facilities	☐ YES	☐ NO
Capacity	☐ YES	☐ NO
Services Offered	☐ YES	☐ NO

**Material changes may include such changes as corporate name, location, addition or deletion of sites that conduct external reviews or addition of major review services.*

6. Describe the Applicant's governing structure, including Board of Directors and standing committees, and the administration and operation of its organization. Indicate the location of the corporate or top-level organization chart in the application.

7. Provide the name of each stockholder or owner of more than five percent (5%) of any stock or options.

SECTION A: CORPORATE PROFILE (continued)

8. Provide the name of any holder of bonds or notes of the Applicant in excess of one hundred thousand dollars ($100,000).

9. Lines of business (check all that apply). ☐ Medicare ☐ Medicaid ☐ Indemnity

☐ Workers' Compensation ☐ Clinical specialty carve out (specify) _____

☐ Utilization Management ☐ CMO ☐ External Review Organization

☐ Network ☐ HMO ☐ PPO ☐ IPA E PHO/PSO

☐ Benefits Administration ☐ Home Health Care ☐ Other_____

10. Provide 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.

11. Provide the name and a biographical sketch of each director, officer, and executive of the Applicant, any entity identified under previous Item 10 of this section, and each reviewer, and a description of any relationship a named individual or the Applicant has with a trade or professional association of providers, trade or association of payers, insurer as defined in KRS 304.17A-600(8), or a provider of health care services in the state of Kentucky.

12. Indicate a percentage of the Applicant's revenues that are anticipated to be derived from independent reviews _____.

13. If the Applicant has delegated certain functions, please list the contracted companies; indicate which services they perform; and provide the information requested below. If no functions have been delegated, check "not applicable" as follows. ☐ Not applicable

For each company, identify the following information:

- Name and title of contact person for the site
- Delegated site street address
- Phone and fax numbers of contact person
- List of services provided
- A copy of the agreement whereby the external review function is delegated or subcontracted

14. a. Has the Applicant ever been refused accreditation or certification to perform external reviews?

☐ YES ☐ NO

b. If yes, please explain

_____

SECTION A: CORPORATE PROFILE (continued)

15. a. Is the Applicant certified to perform external reviews in other states?
☐ YES ☐ NO

b. If yes, list the states_____

_____

16. a. Is the Applicant currently accredited by the National Committee for Quality Assurance?
☐ YES (provide current certificate) ☐ NO

b. If yes, accreditation outcome:
☐ Excellent ☐ Commendable ☐ Accredited ☐ Provisional

- Identify any sanctions imposed or revocations of accreditation to perform external reviews and please explain_____

_____

17. a. Is the Applicant currently accredited by the American Accreditation HealthCare Commission (URAC)? ☐ YES (provide current certificate) ☐ NO

b. If yes, type of accreditation: ☐ Full ☐ Conditional

- Identify any sanctions imposed or revocations of accreditation to perform external reviews and please explain _____

_____

18. Is the Applicant currently accredited by any other national accreditation organization?
☐ YES (provide current certificate) ☐ NO

19. Indicate below any limitations in the type of external reviews performed.

☐ Coverage denial with a medical issue

☐ Experimental/investigational treatments

☐ Medical appropriateness/medical necessity

☐ Experimental/investigational treatments and medical appropriateness/medical necessity

☐ Step therapy exception or step therapy appeal denials
☐ Other

20. Indicate the hours of operation and time zone the Applicant is located in

_____

SECTION B. ADMINISTRATION AND OPERATION

(Must be completed by <u>all</u> Applicants. Indicate not applicable (N/A), where appropriate) Bookmark each of the items below according to the heading of each item below with the appropriate bookmarks for policies and procedures included in the PDF document.

1. **<u>Organization -</u>** Provide a chart of the Applicant's organization which shows the lines of authority and, for key project staff members, their position and level of responsibility within the organization.

2. **<u>Personnel Requirements -</u>** Provide an estimate of the number, types and functions of the personnel considered necessary to the administration and operation of the organization on a statewide basis with a separate job description detailing the roles of key persons, such as a Medical or Clinical Director. Include an explanation of the contractual and financial relationships between the Applicant and the physician and non-physician reviewers who will actually be responsible for individual external reviews. Provide the policy or procedure that demonstrates compliance with KRS 304.17A-627(5) and (6) in regards to the health care professionals utilized to perform reviews and 806 KAR 17:290 Section 3(6).

3. **<u>Credentialing Criteria -</u>** Provide a policy or procedure describing the system used to: identify and recruit expert reviewers; initially credential and, every three (3) years, recredential reviewers, and match expert reviewers to specific cases pursuant to 806 KAR 17:290, Section 3(6). Minimum qualifications/criteria employed by the Applicant to select both physician and non-physician reviewers should be included, as well as a mechanism to ensure that reviewers, particularly physician reviewers, hold in good standing a nonrestricted license in a state of the United States pursuant to KRS 304.17A-627(5) and (6). Provide a copy of each Policy and Procedure relating to credentialing. Also, please list the personnel (reviewers) who may be assigned to external reviews pursuant to KRS 304.17A-627(5) through (7) and 806 KAR 17:290, Section 3(5), including the following information for each reviewer:

- Name;
- Title;
- Professional license (s);
- State (s) of licensure;
- Any restrictions on licensure in the state (s) of licensure;
- Certification by a recognized American specialty board, including type of certification, name of specialty board issuing certification, date of initial certification and subsequent re-certifications, if any, and sanctions imposed, if any;
- Area (s) of expertise;
- Most recent clinical experience and duration of experience;
- Type of cases the reviewer is credentialed to perform; and
- Date of most recent credentialing of the reviewer by Applicant.

SECTION B: ADMINISTRATION AND OPERATION (continued)

4. **Conflict of Interest –** Provide policy or procedure describing how the Applicant will ensure compliance with the conflict of interest rules, including a process that will be used to ensure the independence of the independent review entity, physician and non-physician reviewers in accordance with KRS 304.17A-627 and 806 KAR 17:290, Section 3. Additionally, provide a copy of an attestation form that will be used by the independent review entity to support for each external review that the independent review entity: is not a subsidiary of, or in any way affiliated with, or owned, or controlled by an insurer or a trade or professional association of payors; is not a subsidiary of, or in any way affiliated with, or owned, or controlled by a trade or professional association of providers; does not have any material, professional, familial, or financial conflict of interest with the insurer involved in the external review; any officer, director, or management employee of the insurer involved in the external review; the provider proposing the service or treatment which is being disputed or any associated independent practice association, the institution at which the service or treatment would be provided, the development or manufacture of the principal drug, device, procedure or other therapy proposed for the covered person whose treatment is under review, or the covered person and a copy of a "no conflict of interest" statement that each reviewer will sign prior to conducting an external review to support that the reviewer has no material, professional, familial, or financial conflict of interest with any of the following:

- The insurer involved in the review;
- Any officer, director, or management employee of the insurer;
- The provider proposing the service or treatment or any associated independent practice association;
- The institution at which the service or treatment would be provided;
- The development or manufacture of the principal drug, device, procedure, or other therapy proposed for the covered person whose treatment is under review; or
- The covered person.

5. **External Review for Adverse Determinations, External Reviews of a Coverage Denial, Step Therapy Exception, or Step Therapy Appeal Denials -** Provide a policy or procedure describing all aspects of the external review process, including a schematic chart which shows the process by which an expedited and non-expedited external review will proceed from the time of preliminary review to the final decision, including maximum time required to complete each phase. Include copies of policies and procedures implemented to ensure an independent external review of a coverage denial, which requires the resolution of a medical issue and an adverse determination. The policies and procedures shall address at a minimum the following to demonstrate compliance with KRS 304.17A-163, KRS 304.17A-623, KRS 304.17A-625, KRS 304.17A-627, and 806 KAR 17:290, Section 3:

- **Handling Assignment Requests –** Provide the policy or procedure demonstrating compliance with 806 KAR 17:290, Section 3(1) through (4);

- **Decision Criteria –** Provide the policy or procedure on the information used and the criteria developed to render a decision on an external review pursuant to KRS 304.17A-625 and information from the insurer as outlined in 806 KAR 17:290, Section 2;

- **Decision Timeframes/Extensions –** Provide the policy or procedure for external review decision timeframes pursuant to KRS 304.17A-623(12) and (13) and 806 KAR 17:290, Section 3;

- **Decision Notification/Letter Contents –** Provide the policy or procedure for external review notifications and a copy of each model letter or template used to communicate or request information relating to an external review in accordance with KRS 304.17A-623 and 806 KAR 17:290, Section 3;

- **Fee Charged to Covered Persons –** Provide the policy or procedure demonstrating the process for charging and the process to waive the covered person's fee for the external review pursuant to KRS 304.17A-623(5) and 806 KAR 17:290, Section 5; and

- **Fee Structure for External Reviews –** Provide the policy and procedure used to develop the fee structure and provide a fee schedule for external reviews. Include in the policy or procedure the process for requesting an excess fee to the Department in accordance with the HIPMC-IRE-5 Approval of an External Review Fee in Excess of $800 document. The fee schedule should include the following, 1) Fee to conduct external review of a coverage denial with ~~a~~ medical issues; 2) Fee to conduct a complete (full) external review; and 3) Fee to conduct an incomplete external review where full review is not necessary owing to reversal by the insurer of its adverse determination.

6. **Quality Assurance Program -** Provide a policy or procedure describing the quality assurance program, pursuant to 806 KAR 17:290, Section 3(15).

7. **Records Retention -** Provide a copy of the policies and procedures implemented for the five (5) year maintenance and confidential treatment of external review materials in accordance with Section 3(11) of 806 KAR 17: 290.

8. **Annual Reporting -** Provide a policy or procedure describing the system that will be used to collect, maintain and report data relating to external reviews and a copy of the plan to submit an annual report to the Kentucky Department of Insurance on March 31 of each year, pursuant to 806 KAR 17:290, Section 10.

9. **Accessibility -** Provide a policy or procedure describing the toll-free telephone access system and how requests for external review are coordinated after business hours, weekends, and holidays.

10. **Delegated Functions -** If an external review function or any portion thereof is delegated or subcontracted to another person or organization, provide a description of the oversight activities and how frequently the activities are monitored both on- and off-site (attach a copy of subcontract agreement).

11.**Changes to Policies or Procedures -** Provide a copy of a policy and procedure relating to the written notification of the Department of Insurance of any change to this Application of Certification within thirty (30) days prior to implementation pursuant to 806 KAR 17:290, Section 3(16).

12. **Cessation of Operations -** Provide a policy or procedure demonstrating compliance with 806 KAR 17:290, Section 11.

13. **Complaints -** A copy of policies and procedures relating to the resolution of complaints of covered persons and providers as well as complaints that may be filed with the Kentucky Department of Insurance pursuant to 806 KAR 17:290, Section 8.

SECTION C. CORPORATE ATTESTATION OF APPLICANT

(Must be completed by all Applicants)

On company letterhead, formally attest to the items listed below. The Applicant may use similar language. Have the attestation signed and dated by the appropriate officer(s) of the Applicant's organization and/or legal counsel. This Attestation should be included with the application forms. The Applicant is attesting that the following are true.

1. The information and material contained in this application is true and accurate to the best of my knowledge.
2. The documentation submitted as evidence for meeting Kentucky statutory and regulatory requirements has been reviewed by the appropriate personnel and reflects the Applicant's current structure and processes.

3. The Applicant organization, to the best of its knowledge, is in compliance with applicable state and federal laws governing confidentiality of health care information and state laws as they pertain to the Applicant's business.

4. The Applicant understands that the Department of Insurance will rely on this information and material in making its decision regarding certification and that any distorted facts or misrepresentations may disqualify the Applicant from certification or result in revocation of the certification at any time.