November 9, 2012

Bulletin 193

CERTIFICATION OF INDEPENDENT REVIEW ORGANIZATIONS

This Bulletin is directed to all insurers, as defined by IC 27-8-28-9, and all health maintenance organizations (HMOs) doing business in Indiana, and to all organizations acting as or interested in acting as independent review organizations (IROs) for the external grievance procedures set forth in IC 27-13-10.1 or IC 27-8-29 (collectively, the "IRO laws"). For the purposes of this Bulletin, the term "insurer" refers to both HMOs and insurers. In the event of a material difference between the articles pertaining to HMOs and insurers, IC 27-13-10.1 applies to HMOs and IC 27-8-29 applies to insurers.

Indiana requires each insurer doing business in Indiana to establish and maintain an external review grievance procedure. The Department is required to establish and maintain a process for annual certification of IROs and to maintain a list of certified IROs to be used by insurers. The federal Patient Protection and Affordable Care Act (Publ. Law 111-148) and the Health Care and Education Reconciliation Act (Publ. Law 111-152) (collectively "ACA") directed the federal Department of Health and Human Services (HHS) to promulgate regulations implementing ACA's provisions. Among those regulations were ones relating to IROs. This Bulletin sets forth the procedure for certification, including compliance with requirements promulgated under ACA, and updates and replaces Bulletin 188.

The IRO laws routinely use the term "external grievance," while ACA and HHS regulations use the term "external review." For purposes of this Bulletin, the terms "external grievance" and "external review" have the same meaning.

Request for Certification as an IRO

To be considered for certification, organizations must submit a Request for Certification (Request) to the Department, per instructions found on the Department's web site: www.in.gov/idoi. The Request must comply with all instructions contained in this Bulletin. Incomplete Requests will not be considered. A Request must include the following information:

- Identifiable and specific responses to each criteria set forth in this Bulletin and the IRO laws;
- A statement certifying that all information included in the Request is accurate to the best of the Applicant's knowledge and belief and signed by the Applicant's chief executive officer or an individual authorized to act in similar capacity for the Applicant;
- Consecutive page numbering and identification of sections.
- Written proof that the IRO is "accredited by a private, nationally recognized accrediting organization." This proof shall be submitted as an addendum to the request. The addendum must include a copy of the formal document showing accreditation and must be appropriately titled.

Section 1 – Technical/Procedure

This section must describe the organization's approach and plans for accomplishing the external grievance review process described in the IRO Laws. The organization should describe the effort and skills necessary to complete the process. This section shall contain at least the following information:

1) A summary of the organization's case review process, which demonstrates an understanding of the law governing the external review process.

2) A description of how the work will be accomplished within each step of the case review process. Simple statements that a task will be completed or a reiteration of the criteria are not acceptable. The description should explain the process to be employed in reviewing an insurer's determination and include a flow chart depicting the process by which external review will proceed from the receipt of the Request for review to the final decision. The explanation should address the criteria used in the decision-making process and the systems and methods used to process case reviews, including the following:

a) Process for providing a decision in the statutorily mandated amount of time.

b) Process for selecting and assigning reviewers to cases including the recruitment and contracting, credentialing, and assignment of appropriate specialists to cases.

c) Process for ensuring independence, including any contract provisions with reviewers that require the contracted reviewer to review the case for potential conflicts of interest before accepting the assignment.

d) Process for maintaining the confidentiality of medical and treatment records and any other review materials during communication with parties involved in the review process and during "in house" communication.

e) Process for communication with parties involved in the review process, including any requirements for the process that insurers must follow when submitting the Request for external review and the case file.

f) Process for requesting and receiving additional information from insurers or other parties, including any requirements that responses be submitted by a particular method (i.e. overnight mail, facsimile), and whether the organization will re-contact an insurer if information is not provided in a timely fashion and the process for doing so.

g) Process for rendering and communicating decisions.

h) Process for maintaining written records pertaining to each case review and the retention schedule of those records.

3) A summary of any problems the organization might reasonably expect in the external review process, and anticipated solutions to those problems.

4) A drafted format for the annual report to the Department required by IC 27-13-10.1-8(c)(3) and/or IC 27-8-29-19(c)(3).

5) A description of the statistics maintained by the IRO that will be made available to the Department on request.

Section 2 – Cost

This section must contain all information related to fees to be charged by the IRO to the HMO or insurer.

1) Fees charged for each review should be reasonable in relation to the work performed. Work performed should be broken down into the following review types:

a) Preliminary review;
b) Situations where full review is not necessary owing to reversal by the insurer of its adverse determination due to new information; and
c) Full review.

2) If the fee structure is other than a flat, per case rate, the basis upon which it will be determined, including the anticipated average cost per case.

3) A statement that all fee schedules submitted with the Request will not be increased during the one-year certification period.

Section 3 – Organizational Support and Experience

This section must contain all pertinent information relating to the organization's personnel and experience that would substantiate its qualifications and capabilities to perform external reviews as described in the IRO laws. This section must contain at least the following information:

1) Certification of incorporation or partnership and location of Applicant's headquarters and offices in or nearest to Indiana.

2) Any organization requesting certification as an IRO must provide the following information about the organization and any parent corporation, subsidiary, or affiliate:
a) Name and address of each member of the board of directors;
b) Name and address of any owner, partner or any other person with 10% or more voting shares;

3) A chart illustrating the relationship among all affiliated entities.

4) An internal organizational chart that identifies key grievance review staff members and their responsibilities within the organization; provides an estimate of the number, types, and functions of the personnel considered necessary to the administration and operation of the organization in Indiana with a separate job description detailing the roles of key persons; and describes the contractual and financial relationships between the organization and the clinical personnel who will be responsible for individual case reviews.

5) A list of personnel who may be assigned to individual case reviews. For each reviewer, the list must include the name, professional license(s), board certification(s), and any history of disciplinary actions or sanctions that raise a substantial question as to the reviewer's physical, mental or professional competence or moral character, including loss of staff privileges, or restrictions on participation, taken or pending by any hospital, government or regulatory body.

6) A list of all managed care organizations, hospitals, health care facilities, and other health care providers with whom the organization maintains any health related business arrangements. This list must include a brief description of the nature of any such arrangement.

7) A description of how the organization will:

a) Provide licensed review personnel who possess the appropriate training and qualifications in the medical subject area for which they will be conducting the review, including the criteria to be used for the selection or rejection of review personnel.

b) Ensure the availability of appropriate personnel as needed for timely and efficient review.

c) Ensure the neutrality and objectivity of all personnel conducting external reviews, including avoidance of conflicts of interest or the appearance of a conflict of interest.

8) A description of the organization's quality assurance program for case review.

9) Documentation which clearly shows the organization's experience in performing similar reviews and describes the organization's experience in utilization review, including an explanation of level(s) and scope of involvement in the utilization review process. The organization may also provide a list of references, including entities for which the Applicant has performed similar review under any state or federal external grievance review law.

10) A statement that the organization agrees to accept all eligible cases referred to it on the rotating basis required to be used by insurers.

11) A statement that the organization accepts the following procedure. 45 CFR 147.136(c)(2)(vii) requires that the State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual. Therefore, the Department will maintain an approved list of certified IROs to be used by insurers. Assignments of IROs for eligible cases will be made by the Department sequentially from the approved list, and no insurer will be assigned the same IRO until they have completed the whole list. The list will be regularly updated and posted at www.in.gov/idoi. Insurers may click the "Sign up to receive e-mail and wireless updates from the IDOI" link on the Department's web site to receive automatic updates to the list.

12) A statement that the Request designates agreement to comply with the IRO laws.

13) A list of all professional designations and/or licenses held by the organization and a brief explanation of all credentials held by the organization from other states and credentialing organizations.

14) A description of any disciplinary actions or sanctions taken or ongoing against the organization in the preceding ten (10) years.

Section 4 – Right to Submit Additional Information

This section must contain the organization's approach and plans for complying with a covered individual's right to submit additional information to the IRO and must provide detailed descriptions of how the IRO intends to comply with the following:

1) The covered individual must be notified via telephone, email, or in printed writing, by the IRO performing the external review, of the individual's right to submit additional information.

a) The cost of notification may not be charged to the covered individual;

b) Notification of the right to submit additional information must occur promptly after the individual has filed a request for external review with the IRO;

c) The language of the notification must be concise and clear; and

d) The notification may be included as a section of routine correspondence, provided that it remains distinguished from other correspondence.

2) The covered individual must be provided at least five business days to submit any additional information, provided that this requirement does not otherwise:

a) Prolong the time required to resolve an expedited external review; or

b) Conflict with other provisions of the IRO laws.

3) Any additional information submitted by the covered individual must be forwarded to the insurer within one business day of receipt by the IRO.

Department Review

The Department may:

- Approve any number of entities for certification as IROs;
- Reject any request for certification or re-certification if determined by the Commissioner to be necessary, appropriate, or in the best interests of insurers and their enrollees;
- Suspend, revoke or otherwise sanction an organization's IRO certification if the Commissioner determines that the organization is not in substantial compliance with the information provided in the organization's Request, any applicable law, or any regulation or other guidance issued by the Commissioner;
- Request that an organization alter its activities to be consistent with any applicable law or any regulation or other guidance issued by the Commissioner; or
- Deny or reassign a request for external review if the Commissioner has reason to believe that such an assignment would result in or create the appearance of a conflict of interest or if the Commissioner determines that the organization cannot or has not conducted a review in accordance with the statute.

Timelines

The period of certification is one year. The IRO Certification List shall be published on the Department website: http://www.in.gov/idoi.

IRO certification and/or re-certification is performed on an annual basis. Requests for certification or re-certification must be delivered to the Department on or before December 1 of each year.

Submission of Request

Requests should be submitted electronically to Rebecca Vaughan at *rvaughan@idoi.IN.gov*, in Microsoft Word or PDF format.

INDIANA DEPARTMENT OF INSURANCE

Stephen W. Robertson,
Insurance Commissioner