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**Rules of**  
**Department of Insurance,**  
**Financial Institutions and**  
**Professional Registration**  
**Division 100—Insurer Conduct**  
**Chapter 5—Health Care Consumer Procedures**

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**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION**  
**Division 100—Insurer Conduct**  
**Chapter 5—Health Care Consumer  
Procedures**

**20 CSR 100-5.010 Notice Requirements of  
an Adverse Determination**

*PURPOSE: This rule sets forth with greater specificity the requirements of written notification when a health carrier informs an enrollee of a health plan that includes a managed care component of an adverse determination. This rule is promulgated pursuant to section 376.1399, RSMo, and implements section 376.1363.5, RSMo.*

(1) A written notification of an adverse determination shall be printed in clear legible type of at least twelve (12)-point font.

(2) The notice shall explain the principal reason for the adverse determination in language easily understood by a person with an eighth grade reading level. A health carrier may determine the reading level of a notice without including medical terminology which describes an enrollee's medical condition, proper names, telephone numbers and addresses.

(3) The notice shall explain how an enrollee initiates a grievance review. If an enrollee is eligible for an expedited review pursuant to section 376.1389, RSMo, then the notice shall explain how an enrollee initiates an expedited review.

(4) The notice shall explain how an enrollee as defined in section 376.1350(14), RSMo initiates a grievance review of the adverse determination with the director. The notice shall explain that an enrollee may file a grievance with the director at any time. The notice shall also list the Consumer Affairs Division's toll-free telephone number.

(5) The notice shall describe how the enrollee can request a written statement of the clinical rationale and clinical review criteria used to make the adverse determination.

(6) If the Health Care Financing Administration's Medicare or Medicaid plans have notification requirements for grievance procedures, those notification requirements shall satisfy the requirements of this rule for notification of enrollees in those plans if the

notices comply with all Missouri statutory requirements.

(7) The notice shall inform enrollees that they have a right to have a relative, friend, lawyer, the department or other representative help them with a grievance.

*AUTHORITY: sections 374.045 and 376.1363.5, RSMo 2000 and section 376.1399, RSMo Supp. 2007.\* Original rule filed Nov. 3, 1997, effective June 30, 1998. Amended: Filed Nov. 1, 2007, effective July 30, 2008.*

*\*Original authority: 374.045, RSMo 1967, amended 1993, 1995; 376.1363, RSMo 1997; and 376.1399, RSMo 1997, amended 1997, 2007.*

**20 CSR 100-5.020 Grievance Review Procedures**

*PURPOSE: This rule sets forth with greater specificity the procedures by which the department will process a grievance concerning an adverse determination by a health carrier or its designee for a health plan that has a managed care component. This rule is promulgated pursuant to section 376.1399, RSMo, and implements section 376.1387, RSMo.*

(1) As used in this rule, "division" means the Consumer Affairs Division.

(2) As used in this rule, "enrollee's representative" or "representative" means—

(A) A person to whom an enrollee has given express written consent to represent the enrollee in an external review;

(B) A person authorized by law to provide substituted consent for an enrollee; or

(C) A family member of the enrollee or the enrollee's treating health care professional only when the enrollee is unable to provide consent.

(3) When a health carrier, as defined by section 376.1350(22), RSMo, or their designee utilization review organization issues an adverse determination, as defined by section 376.1350(1), RSMo, to an enrollee in a health plan that has a managed care component, the enrollee or his/her representative may file a grievance with the director without exhausting all remedies available under the carrier's grievance process. Medicaid participants also may use the division's grievance process in an effort to resolve an adverse determination; however, the director may not have the authority to issue an order in such cases.

(4) A health carrier or plan sponsor also may file a grievance with the director concerning an adverse determination.

(5) A grievance will be processed by the division as any other consumer complaint. The division will assign the grievance a file number. The division will send an inquiry to the health carrier (or party) which is complained against requesting the health carrier (or party) to respond in writing with their position and all supporting documentation concerning the matter grieved. The division will attempt to resolve the issue with the health carrier (or party).

(6) If the director determines a grievance is unresolved after completion of the division's consumer complaint process, the director shall refer the unresolved grievance to an independent review organization (IRO). An unresolved grievance shall include a difference of opinion between a treating health care professional and the health carrier concerning the medical necessity, appropriateness, health care setting, level of care, or effectiveness of a health care service.

(7) The director shall seek the services of an IRO(s) by competitive bid pursuant to Chapter 34, RSMo. Any IRO selected through the competitive bid process shall be accredited by a nationally-recognized private accrediting organization. The department shall maintain a current list of IROs under contract with the department on its website.

(8) An IRO shall maintain written policies and procedures governing all aspects of the external review process that include a quality assurance mechanism that, at a minimum—

(A) Ensures the selection of qualified and impartial clinical peers to conduct external reviews on behalf of the IRO;

(B) Ensures assignment of clinical peers to specific cases related to their area(s) of expertise;

(C) Ensures that the IRO employs or contracts with an adequate number of clinical peers to meet the foregoing objectives;

(D) Ensures that external reviews are conducted within the specified time frames and required notices are provided in a timely manner;

(E) Ensures the confidentiality of medical and treatment records and clinical review criteria; and

(F) Ensures that any person employed by or under contract with the IRO adheres to the requirements of subsections (8)(D) and (8)(E).



(9) An IRO may not own or control, be a subsidiary of, or in any way be owned or controlled by, or exercise control with a health carrier; a national, state, or local trade association of health carriers; or a national, state, or local trade association of health care providers. Neither the IRO selected to conduct the external review nor the clinical peer assigned by the IRO to conduct the external review may have a material, professional, familial, or financial conflict of interest with any of the following:

(A) The health carrier that is the subject of the external review;

(B) The enrollee whose treatment is the subject of the external review or the enrollee's authorized representative;

(C) Any officer, director, or management employee of the health carrier that is the subject of the external review;

(D) The health care provider, the health care provider's medical group, or independent practice association recommending the health care service or treatment that is the subject of the external review;

(E) The facility at which the recommended health care service or treatment would be provided, if known; or

(F) The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the enrollee whose treatment is the subject of the external review.

(10) The director will provide the IRO and the enrollee, enrollee's representative, or health carrier copies of all medical records and any other relevant documents which the division has received from any party. The enrollee, enrollee's representative, and health carrier may review all the information submitted to the IRO for consideration.

(11) The enrollee, enrollee's representative, or health carrier may also submit additional information to the division which the division shall forward to the IRO. All additional information must be received by the division. If an enrollee, enrollee's representative, or health carrier has information which contradicts information already provided the IRO, they should provide it as additional information. All additional information should be received by the division within fifteen (15) working days from the date the division mailed that party copies of the information provided the IRO. An envelope's postmark shall determine the date of mailing. Information may be submitted to the division by means other than mail if it is in writing, typeset, or easily transferred into typeset by the division's technology and a date of transmission is easily

determined by the division. Any additional information submitted by the enrollee or the enrollee's representative shall be reviewed by the IRO when conducting the external review. At the director's discretion, additional information which is received past the fifteen- (15-) working-day deadline may be submitted to the IRO.

(12) The IRO shall request from the division any additional information it wants. The division shall gather the requested information from an enrollee, enrollee's representative, or health carrier or other appropriate entity and provide it to the IRO. If the division is unable to obtain the requested information, the IRO shall base its opinion on the information already provided.

(13) Within twenty (20) calendar days of the receipt of the request for external review, the IRO shall submit to the director its opinion of the issues reviewed. Under exceptional circumstances, if the IRO requires additional time to complete its review, it should request in writing from the director an extension in the time to process the review, not to exceed five (5) calendar days. Such a request should include the reasons for the request and a specific time at which the review is expected to be complete.

(14) After the director receives the IRO's opinion, the director shall issue a decision which shall be binding upon the enrollee and the health carrier. The director's decision shall be in writing and must be provided to the enrollee and health carrier within twenty-five (25) calendar days of receiving the IRO's opinion. In no event shall the time between the date the IRO receives the request for external review and the date the enrollee and the health carrier are notified of the director's decision be longer than forty-five (45) days.

(15) An enrollee or enrollee's representative or health carrier may request an expedited external review if the adverse determination—

(A) Concerns an admission, availability of care, continued stay, or health care service for which the enrollee received emergency services, but has not been discharged from a facility; or

(B) Involves a medical condition for which the delay occasioned by the standard external review time frame would jeopardize the life or health of the enrollee or jeopardize the enrollee's prognosis or ability to regain maximum function.

(16) As expeditiously as possible after receipt

of the request for expedited external review by the IRO, the IRO must issue its opinion as to whether the adverse determination should be upheld or reversed and submit its opinion to the director. As expeditiously as possible, but within no more than seventy-two (72) hours after the receipt of the request for expedited external review by the IRO, the director shall issue notice to the enrollee and the health carrier of the director's determination and may issue a decision to uphold or reverse the adverse determination. If the notice is not in writing, the director must provide the written decision within forty-eight (48) hours after the date of the notice of the determination.

(17) If a request for external review of an adverse determination involves a denial of coverage based on a determination that the health care service or treatment recommended or requested is experimental or investigational, the following additional requirements must be met:

(A) The IRO shall make a preliminary determination as to whether the recommended or requested health care service or treatment that is the subject of the adverse determination is a covered benefit under the person's health benefit plan except for the health carrier's determination that the service or treatment is experimental or investigational for a particular medical condition; and is not explicitly listed as an excluded benefit under the enrollee's health benefit plan with the health carrier;

(B) The request for external review of an adverse determination involving a denial of coverage based on a health carrier's determination that the health care service or treatment recommended or requested is experimental or investigational must include a certification from the enrollee's physician that—

1. Standard health care services or treatments have not been effective in improving the condition of the enrollee; or

2. Standard health care services or treatments are not medically appropriate for the enrollee; or

3. There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the recommended or requested health care service or treatment; and

4. The request for external review of an adverse determination involving the denial of coverage based on a determination that the requested treatment is experimental or investigational shall also include documentation a) that the enrollee's treating physician has recommended a health care service or treatment



that the physician certifies, in writing, is likely to be more beneficial to the enrollee, in the physician's opinion, than any available standard health care services or treatments; or b) that the enrollee's treating physician, who is a licensed, board-certified, or board-eligible physician qualified to practice in the area of medicine appropriate to treat the enrollee's condition, has certified in writing that scientifically-valid studies using accepted protocols demonstrate that the health care service or treatment requested by the enrollee that is the subject of the adverse determination is likely to be more beneficial to the enrollee than any available standard health care services or treatments;

(C) When conducting such an external review, the IRO must select one (1) or more clinical peers, who must be physicians or other health care professionals who meet minimum qualifications and through clinical experience in the past three (3) years are experts in the treatment of the enrollee's condition and knowledgeable about the recommended or requested health care service or treatment. Each clinical peer shall provide a written opinion to the assigned IRO on whether the recommended or requested health care service or treatment should be covered; and

(D) Each such clinical peer's opinion submitted to the IRO shall include the following information:

1. A description of the enrollee's medical condition;
2. A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is more likely than not to be beneficial to the enrollee than any available standard health care services or treatments and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments;
3. A description and analysis of any medical or scientific evidence considered in reaching the opinion;
4. Information on whether the reviewer's rationale for the opinion is based upon whether the recommended or requested health care service or treatment has been approved by the federal Food and Drug Administration for the condition, or whether medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care

service or treatment and the adverse risks of the recommended or requested health care service or treatment would not substantially be increased over those of available standard health care services or treatments; and

5. A description and analysis of any evidence-based standard.

*AUTHORITY: section 376.1387, RSMo 2000, and sections 374.045 and 376.1399, RSMo Supp. 2011.\* Original rule filed Nov. 3, 1997, effective June 30, 1998. Amended: Filed Nov. 1, 2007, effective July 30, 2008. Emergency amendment filed Nov. 15, 2011, effective Jan. 1, 2012, expired June 28, 2012. Amended: Filed Nov. 15, 2011, effective June 30, 2012.*

*\*Original authority: 374.045, RSMo 1967, amended 1993, 1995, 2008; 376.1387, RSMo 1997; and 376.1399, RSMo 1997, amended 1997, 2007.*