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To: External Review Agencies under contract with the Department of Public Health pursuant to M.G.L. c. 176O, § 14

cc: Commercial Health Insurers, Blue Cross Blue Shield of Massachusetts, and Health Maintenance Organizations Accredited Pursuant to M.G.L. c. 176O

From: Karen Granoff, Director, Office of Patient Protection

Re: External Review Decisions

Date: December 11, 2002

M.G.L. c. 176O has been in effect since January 1, 2001. Based on experience to date, the Office of Patient Protection (OPP) would like to clarify its expectations regarding the decisions being rendered by the three external review agencies (ERAs) with whom it contracts.

1. Decisions should be issued as quickly as possible. Although Massachusetts law allows ERAs five business days for expedited reviews and 60 business days for standard (non-expedited) reviews, OPP expects standard reviews to be completed in 30 business days or less, unless the ERA is having difficulty in obtaining medical records or notifies OPP of other extenuating circumstances.

2. If additional information is deemed necessary by the reviewer, such information should be requested. If the reviewer has requested records and the health plan, provider or patient has not provided them, the ERA should contact OPP for assistance. There are remedies available in 105 CMR 128.412 where a health plan has failed to make a good faith effort to obtain requested information. A reviewer should not issue a determination without *requesting* pertinent records unless the evidence is so overwhelming that the missing information would not have influenced the outcome, and should so state in the decision.

3. If an external review agency, or the ERA's reviewer, is uncertain what question is to be answered in any case, it is important for the ERA to contact OPP to obtain the needed clarification.

According to Massachusetts law, "[t]he standard for review of a grievance by [an external review agency] shall be a determination of whether the requested treatment or service is medically

necessary, as defined herein, and a covered benefit under the policy or contract." (M.G.L. c. 176O, § 14(a).) In many, if not most, cases, the external reviewer's task is completed when he or she opines on the medical necessity of a given treatment or service. If the requested treatment or service is determined to be medically necessary, then it must be covered by the health plan.

Occasionally, however, a request is presented in which the reviewer must make a two-part determination in accordance with the above-noted section of the law: if the service is in fact medically necessary, is it a covered benefit under the policy or contract? One example is cosmetic procedures. A health plan contract might state that cosmetic procedures are covered only if related to an illness, or only if related to a functional defect. If an insured is requesting a certain procedure that the health plan has determined to be cosmetic, OPP would send the case out for external review in order that an independent medical professional might render an opinion. In such a case, the reviewer must do a two-part analysis: does the requested service or treatment meet the definition of medical necessity, and, if so, does it then also meet the requirement set forth in the health plan. Only if both parts of the question can be answered in the affirmative would it be appropriate for the reviewer to overturn the health plan's decision.

Similarly, a plan might provide a 60-day benefit for physical therapy for each illness or injury. A patient might request a review of a denial of physical therapy where the health plan has determined that the patient has exhausted the 60-day benefit while the patient's physician argues that the course of treatment is for a new condition. In this case, the reviewer must determine whether the requested physical therapy is medically necessary. As a second step, the reviewer must then determine whether the medical records indicate that the physical therapy is for the original diagnosis or is for a new condition separate from that for which the 60-day benefit was exhausted. Again, only if the reviewer finds that the requested physical therapy is medically necessary *and* that it is for a new condition unrelated to the original 60-day benefit should the reviewer overturn the health plan's denial of coverage.

Another example of a two-part analysis involves requests to see out-of-network providers. In these cases, the reviewer must look at the patient's presenting illness and the proposed or requested treatment, and answer two questions. The first is whether the proposed treatment is medically necessary. The second is whether either the illness or proposed treatment is so complex or unique that it is medically necessary that the patient receive the care from that particular provider because there are no in-network providers who could render the treatment. Again, only if both questions are answered in the affirmative is it appropriate for a reviewer to overturn a health plan's original denial.

If OPP determines that a requested service or supply is clearly an exclusion under the terms of the health plan contract, OPP advises the insured that the request is not eligible for external review, and does not send out the case. Since OPP screens out cases where there is a clear exclusion, external reviewers should not have to complete any analysis beyond the two steps noted above.

4. External review agency decisions must, at a minimum, contain the following information:

- The credentials of the reviewer or reviewers.
- The patient's presenting symptoms or condition, diagnosis and treatment interventions.
- The recommendations of the treating physician (the service or supply that is being requested).
- The health plan's rationale for the adverse determination, including a discussion of the health plan's clinical review criteria, if relevant.
- The information considered during the review process, including an itemized list of specific records or correspondence and any information supplied by the patient.
- The Massachusetts definition of "medical necessity" and the reviewer's analysis of why the requested service does or does not meet that definition, including the specific medical evidence used in making the determination of whether the requested service or supply is medically necessary.
- The clinical rationale for the reviewer's determination, citing any national standards or relevant published studies used. If the reviewer disregards available studies or guidelines, the reviewer must present a clear explanation of their inapplicability to the case under review.
- If there is relevant contract language, a discussion of the parameters of coverage and the analysis of why the requested service does or does not meet the contract limitations.

5. For decisions that involve services denied by the health plan as experimental or investigational, the reviewer must cite reliable evidence to support the decision. Reliable evidence is defined as one or more of the following regarding the effectiveness and efficacy of the proposed treatment:

- Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not a part of the editorial staff;
- Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database Health Services Technology Assessment Research (HSTAR);
- Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act;
- The following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information;
- Findings, studies and research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office

of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services;and

- Any other medical or scientific evidence that is comparable to those listed above.

Medical or scientific evidence shall not include published peer-reviewed literature sponsored to a significant extent by a pharaceutical manufacturing company or medical device manufacturer.

OPP recognizes that in certain instances involving extremely rare conditions, there may not be any reliable evidence as defined above regarding proposed treatments. In those instances, the ERA must cite scientific evidence to support its decision.

6. Decisions by an ERA must be consistent. ERAs must review decisions regarding same or similar requests and validate the consistency of decisions from reviewer to reviewer. An ERA should not release a decision without checking previous cases for similarities. When two reviewers come to opposite conclusions, the ERA must be prepared to reconcile the cases to OPP and to the health plans, either by clearly distinguishing the presenting facts of each case or by documenting a change in the supporting evidence. If there is a change in a determination regarding the experimental or investigational status of a particular service, the ERA must support the change with evidence cited above.