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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: Carol Balulescu, Director, Office of Patient Protection

Re: External Review Decisions of Services Deemed to be Experimental/Investigational

Date: April 1, 2008

The Office of Patient Protection (OPP) would like to clarify its expectations regarding the process of external review of services that a health plan has deemed to be investigational or experimental.

As noted in the advisory memo that OPP issued on December 11, 2002, OPP expects the following of external review agencies:

> **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 pharmaceutical 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.

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.

Additionally, OPP expects that in cases where an appellant is seeking a retrospective review of already-provided services, reviewers will make a decision based on the date on which the services were rendered. Reviewers should not rely on evidence that was not published or otherwise available on the date the service was rendered.

OPP has developed the enclosed guidance for review of decisions for services considered to be experimental or investigational and asks that the document be provided to each reviewer at the time the case is sent out. In addition, OPP will include a cover letter with each such case to remind the ERA of OPP's expectations and to identify services for which OPP may have received differing opinions. In many, if not most of the cases involving experimental/investigational treatments, OPP will ask that the ERA use a three-reviewer panel in order to render its decision. OPP also expects the ERAs to identify cases in which a three-reviewer panel will ensure a more thorough review of the services in question if OPP has not done so.

OPP is hopeful that this guidance and proposed additional screening and identification by OPP will result in a better external review process that is fair to patient, providers, and health plans.

If you have any questions, please call me at 617-624-5216 or email me at carol.balulescu@state.ma.us.