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January 20, 2009

RE: AN ACT to amend the public health law  
and the insurance law, in relation to  
protocol for treatment of rare disease.

A.301 (Millman)

**MEMORANDUM IN OPPOSITION**

Submitted on behalf of the  
Blue Cross and Blue Shield Plans

The Blue Cross and Blue Shield Plans of New York oppose enactment of this legislation, which seeks to unnecessarily and unjustifiably relax the existing standard used in medical necessity determinations for not only external appeals but internal utilization review decisions for a specified and expanding set of rare diseases which are listed by the National Institutes of Health Office of Rare Diseases.

1. **THE PROPOSED LEGISLATION IS UNJUSTIFIED AS THE NATIONAL INSTITUTES OF HEALTH OFFICE OF RARE DISEASES' LIST IS OVERLY INCLUSIVE.**

If enacted, this Legislation would prescribe the special external review standard reserved for experimental or investigational treatments for all diseases listed as a rare disease by the National Institutes of Health Office of Rare Diseases (ORD). In order to qualify as a rare disease, and in turn be listed, a disease must affect fewer than 200,000 individuals in the United States. Furthermore, certain diseases with 200,000 or more affected individuals may be included if sub-populations of these conditions are equal to 200,000 affected individuals. While the compilation of such a list is laudable, currently ORD lists over 6,800 rare diseases on the website that either affect fewer than 200,000 individuals or represent a condition for which information requests have been made to ORD. Therefore, it is not discernable which diseases are in fact rare and which are listed as a result of an information request.

2. **THE PROPOSED LEGISLATION WOULD UNNECESSARILY CHANGE THE STANDARD USED BY EXTERNAL APPEAL AGENTS TO REVIEW APPEALS BASED ON MEDICAL NECESSITY FOR RARE DISEASES.**

The current external review standard for medical necessity which provides that an external appeals agent shall make determination “as to whether the health care plan acted reasonably and with sound medical judgement and in the best interests of the patient” has proven to be an effective process to provide an independent review of claims determinations based on conventional medical theories. If enacted, this bill would unjustifiably relax the existing standard for rare diseases to mirror the special standard enacted for experimental or investigational external appeals.

The special standard that requires plans to cover treatments that are likely to be more beneficial to the insured than any standard health service or procedure is not sensible outside of appeals for experimental or investigational services. For example, it might be reasonable and in sound medical judgment to deny many experimental or investigational treatments, as there is usually limited data available on these services, they involve a certain measure of risk, and their effectiveness is yet to be determined. Thus, the standard currently applied to medical necessity determinations (whether the plan acted reasonably, with sound medical judgment and in the best interest of the patient) does not suit appeals for experimental or investigational treatments.

Sponsors of this Legislation argue that the special standard should be applied for rare diseases because there “is little economic incentive for undertaking expensive clinical trials for rare disease treatments.” However, unlike experimental or investigational services, where the effectiveness of treatments has yet to be determined and therefore necessitates the relaxed standard, many rare diseases have existing proven treatments which can be reviewed using the existing medical necessity standard. For instance, Acromegaly, a syndrome associated with the pituitary gland which results in the over-production of growth hormone, is listed as a rare disease and has a number of proven treatments including surgery and drug therapy. In addition, Ehrlichiosis, a tick borne bacterial disease, is listed which has proven antibiotic medical treatment.

3. **THE PROPOSED LEGISLATION SEEKS TO IMPOSE A “LIKELY TO BENEFIT” STANDARD ON INTERNAL PLAN UTILIZATION REVIEW OF RARE DISEASES WHICH IS NOT EVEN IMPOSED FOR EXPERIMENTAL OR INVESTIGATIONAL SERVICES.**

The current utilization review law represents an efficient process to provide internal plan review of claims determinations based on conventional medical theories. If enacted, this bill would result in the existence of two competing standards to be used in medical necessity review without providing any justification for the proposed relaxed standard for a list of approximately 6,800 rare diseases which can be and are currently reviewed based on medical necessity. This bill would add identical provisions to sections 4905 of the public health law and section 4905 of the insurance law to include the following language:

When making determinations in relation to rare disease treatment, the utilization review agent shall review medical and scientific evidence relating to conditions or diseases of higher prevalence in the same class or category, determined by the review agent to be comparable to the rare disease, as well as medical and scientific evidence relating to the rare disease, in order to determine whether the treatment is likely to benefit the patient, if the specific health treatment or service recommended by the health care professional would not otherwise be excluded from coverage under the policy on grounds other than medical necessity or experimental treatment

The additional standard: that the utilization review agent must “review medical and scientific evidence relating to conditions or diseases of higher prevalence in the same class or category, determined by the review agent to be comparable to the rare disease, as well as medical and scientific evidence relating to the rare disease, in order to determine whether the treatment is likely to benefit the patient” purports to apply a relaxed standard, rightfully reserved for experimental and investigation treatments in external review, to utilization review agent determinations for a specified list of rare diseases that have proven medical treatments. Furthermore, the added provision would require utilization review agents to review medical evidence relating to diseases in “the same class or category” without any guidance as to what would qualify a disease of higher prevalence to be in the same class or category. Thus, passage of this bill would create confusion in medical necessity utilization review and would set forth an unjustified relaxed standard for a myriad of rare diseases.

4. **THE PROPOSED LEGISLATION WOULD CAUSE AN UNNECESSARY INCREASE IN PREMIUMS BY ENCOURAGING THE USE OF MEDICALLY UNNECESSARY SERVICES.**

An important cost control for health insurers is the ability to deny coverage for unnecessary services. This legislation would make it more difficult to sustain denials of medically unnecessary services and would encourage providers to recommend more unnecessary services and enable insureds to utilize services that will not improve their health. This will result in the waste of premium dollars on such speculative services and higher premiums for all insureds, including those who appropriately utilize health services.

For these reasons, the Blue Cross and Blue Shield Plans strongly urge that this bill not be enacted into law.

Respectfully submitted,

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Blue Cross and Blue Shield Plans