S T A T E O F N E W Y O R K

3840

2009-2010 Regular Sessions

I N S E N A T E

April 2, 2009

Introduced by Sen. DUANE -- read twice and ordered printed, and when printed to be committed to the Committee on Health

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

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Section 4900 of the public health law is amended by adding a new subdivision 11 to read as follows:

11. "RARE DISEASE TREATMENT" MEANS A TREATMENT OR SERVICE ADMINISTERED TO AN ENROLLEE WITH A RARE DISABLING OR LIFE-THREATENING CONDITION OR DISEASE WHICH IS LISTED AS A RARE DISEASE BY THE NATIONAL INSTITUTES OF HEALTH OFFICE OF RARE DISEASES OR IS ELIGIBLE FOR SUCH LISTING UNDER THE FEDERAL RARE DISEASES ACT OF 2002.

S 2. Section 4905 of the public health law is amended by adding a new subdivision 16 to read as follows:

16. 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.

S 3. Subparagraphs (ii) and (iii) of paragraph (b) of subdivision 2 of section 4910 of the public health law, as added by chapter 586 of the laws of 1998, are amended to read as follows:

(ii) the enrollee's attending physician has certified that the enrollee has a life-threatening or disabling condition or disease (a) for which standard health services or procedures have been ineffective or

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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would be medically inappropriate, or (b) for which there does not exist a more beneficial standard health service or procedure covered by the health care plan, or (c) for which there exists a clinical trial OR RARE DISEASE TREATMENT, and

(iii) the enrollee's attending physician, who must be a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's life threatening or disabling condition or disease, must have recommended either (a) a health service or procedure (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph [b] (B) of subdivision five of section forty-nine hundred of this article) that, based on two documents from the available medical and scientific evidence, is likely to be more beneficial to the enrollee than any covered standard health service or procedure; or (b) a clinical trial OR RARE DISEASE TREATMENT for which the enrollee is eligible. Any physician certification provided under this section shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation, and

S 4. Item 1 of clause (ii) of subparagraph (B) of paragraph (d) of subdivision 2 of section 4914 of the public health law, as added by chapter 586 of the laws of 1998, is amended and a new subdivision 2-a is added to read as follows:

(1) that the patient costs of the proposed health service or procedure shall be covered by the health care plan either: when a majority of the panel of reviewers determines, upon review of the applicable medical and scientific evidence (or upon confirmation that the recommended treatment is a clinical trial OR RARE DISEASE TREATMENT), the enrollee's medical record, and any other pertinent information, that the proposed health service or treatment (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph (b) of subdivision five of section forty-nine hundred of this article) is likely to be more beneficial than any standard treatment or treatments for the enrollee's life-threatening or disabling condition or disease (or, in the case of a clinical trial OR RARE DISEASE TREATMENT, is likely to benefit the enrollee in the treatment of the enrollee's condition or disease); or when a reviewing panel is evenly divided as to a determination concerning coverage of the health service or procedure, or

2-A. FOR EXTERNAL APPEALS REQUESTED IN RELATION TO RARE DISEASE TREATMENT UNDER ITEM ONE OF CLAUSE (II) OF SUBPARAGRAPH (B) OF PARAGRAPH (D) OF SUBDIVISION TWO OF THIS SECTION, THE EXTERNAL APPEALS AGENT SHALL REVIEW MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO CONDITIONS OR DISEASES OF HIGHER PREVALENCE IN THE SAME CLASS OR CATEGORY, DETERMINED BY THE EXTERNAL APPEALS 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.

S 5. Section 4900 of the insurance law is amended by adding a new subsection (k) to read as follows:

(K) "RARE DISEASE TREATMENT" MEANS A TREATMENT OR SERVICE ADMINISTERED TO AN INSURED WITH A RARE DISABLING OR LIFE-THREATENING CONDITION OR DISEASE WHICH IS LISTED AS A RARE DISEASE BY THE NATIONAL INSTITUTES OF HEALTH OFFICE OF RARE DISEASES OR IS ELIGIBLE FOR SUCH LISTING UNDER THE FEDERAL RARE DISEASES ACT OF 2002.

S 6. Section 4905 of the insurance law is amended by adding a new subsection (p) to read as follows:

(P) 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.

S 7. Subparagraphs (B) and (C) of paragraph 2 of subsection (b) of section 4910 of the insurance law, as added by chapter 586 of the laws of 1998, are amended to read as follows:

(B) the insured's attending physician has certified that the insured has a life-threatening or disabling condition or disease (a) for which standard health services or procedures have been ineffective or would be medically inappropriate, or (b) for which there does not exist a more beneficial standard health service or procedure covered by the health care plan, or (c) for which there exists a clinical trial OR RARE DISEASE TREATMENT, and

(C) the insured's attending physician, who must be a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's life-threatening or disabling condition or disease, must have recommended either (a) a health service or procedure (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph two of subsection (e) of section four thousand nine hundred of this article) that, based on two documents from the available medical and scientific evidence, is likely to be more beneficial to the insured than any covered standard health service or procedure; or (b) a clinical trial OR RARE DISEASE TREATMENT for which the insured is eligible. Any physician certification provided under this section shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation, and

S 8. Item (a) of clause (ii) of subparagraph (B) of paragraph 4 of subsection (b) of section 4914 of the insurance law, as added by chapter 586 of the laws of 1998, is amended and a new subsection (b-1) is added to read as follows:

(a) that the patient costs of the proposed health service or procedure shall be covered by the health care plan either: when a majority of the panel of reviewers determines, upon review of the applicable medical and scientific evidence (or upon confirmation that the recommended treatment is a clinical trial OR RARE DISEASE TREATMENT), the insured's medical record, and any other pertinent information, that the proposed health service or treatment (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph two of subsection (e) of section four thousand nine hundred of this article) is likely to be more beneficial than any standard treatment or treatments for the insured's life-threatening or disabling condition or disease (or, in the case of a clinical trial OR RARE DISEASE TREATMENT, is likely to benefit the insured in the treatment of the insured's condition or disease); or when a reviewing panel is evenly divided as to a determination concerning coverage of the health service or procedure, or

(B-1) FOR EXTERNAL APPEALS REQUESTED IN RELATION TO RARE DISEASE TREATMENT UNDER ITEM (A) OF CLAUSE (II) OF SUBPARAGRAPH (B) OF PARAGRAPH

FOUR OF SUBSECTION (B) OF THIS SECTION, THE EXTERNAL APPEAL AGENT SHALL REVIEW MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO CONDITIONS OR DISEASES OF HIGHER PREVALENCE IN THE SAME CLASS OR CATEGORY, DETERMINED BY THE EXTERNAL APPEAL 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.

S 9. This act shall take effect immediately and shall apply to any utilization review, external appeal, or action or proceeding relating thereto, pending on and after such effective date.