

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:

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

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

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

10 16. WHEN MAKING DETERMINATIONS IN RELATION TO RARE DISEASE TREATMENT,
11 THE UTILIZATION REVIEW AGENT SHALL REVIEW MEDICAL AND SCIENTIFIC
12 EVIDENCE RELATING TO CONDITIONS OR DISEASES OF HIGHER PREVALENCE IN THE
13 SAME CLASS OR CATEGORY, DETERMINED BY THE REVIEW AGENT TO BE COMPARABLE
14 TO THE RARE DISEASE, AS WELL AS MEDICAL AND SCIENTIFIC EVIDENCE RELATING
15 TO THE RARE DISEASE, IN ORDER TO DETERMINE WHETHER THE TREATMENT IS
16 LIKELY TO BENEFIT THE PATIENT, IF THE SPECIFIC HEALTH TREATMENT OR
17 SERVICE RECOMMENDED BY THE HEALTH CARE PROFESSIONAL WOULD NOT OTHERWISE
18 BE EXCLUDED FROM COVERAGE UNDER THE POLICY ON GROUNDS OTHER THAN MEDICAL
19 NECESSITY OR EXPERIMENTAL TREATMENT.

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

23 (ii) the enrollee's attending physician has certified that the enrol-
24 lee has a life-threatening or disabling condition or disease (a) for
25 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.

LBD01759-01-9

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

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

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

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

38 2-A. FOR EXTERNAL APPEALS REQUESTED IN RELATION TO RARE DISEASE TREAT-
39 MENT UNDER ITEM ONE OF CLAUSE (II) OF SUBPARAGRAPH (B) OF PARAGRAPH (D)
40 OF SUBDIVISION TWO OF THIS SECTION, THE EXTERNAL APPEALS AGENT SHALL
41 REVIEW MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO CONDITIONS OR
42 DISEASES OF HIGHER PREVALENCE IN THE SAME CLASS OR CATEGORY, DETERMINED
43 BY THE EXTERNAL APPEALS AGENT TO BE COMPARABLE TO THE RARE DISEASE, AS
44 WELL AS MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO THE RARE DISEASE, IN
45 ORDER TO DETERMINE WHETHER THE TREATMENT IS LIKELY TO BENEFIT THE
46 PATIENT, IF THE SPECIFIC HEALTH TREATMENT OR SERVICE RECOMMENDED BY THE
47 HEALTH CARE PROFESSIONAL WOULD NOT OTHERWISE BE EXCLUDED FROM COVERAGE
48 UNDER THE POLICY ON GROUNDS OTHER THAN MEDICAL NECESSITY OR EXPERIMENTAL
49 TREATMENT.

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

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

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

3 (P) WHEN MAKING DETERMINATIONS IN RELATION TO RARE DISEASE TREATMENT,
4 THE UTILIZATION REVIEW AGENT SHALL REVIEW MEDICAL AND SCIENTIFIC
5 EVIDENCE RELATING TO CONDITIONS OR DISEASES OF HIGHER PREVALENCE IN THE
6 SAME CLASS OR CATEGORY, DETERMINED BY THE REVIEW AGENT TO BE COMPARABLE
7 TO THE RARE DISEASE, AS WELL AS MEDICAL AND SCIENTIFIC EVIDENCE RELATING
8 TO THE RARE DISEASE, IN ORDER TO DETERMINE WHETHER THE TREATMENT IS
9 LIKELY TO BENEFIT THE PATIENT, IF THE SPECIFIC HEALTH TREATMENT OR
10 SERVICE RECOMMENDED BY THE HEALTH CARE PROFESSIONAL WOULD NOT OTHERWISE
11 BE EXCLUDED FROM COVERAGE UNDER THE POLICY ON GROUNDS OTHER THAN MEDICAL
12 NECESSITY OR EXPERIMENTAL TREATMENT.

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

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

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

36 S 8. Item (a) of clause (ii) of subparagraph (B) of paragraph 4 of
37 subsection (b) of section 4914 of the insurance law, as added by chapter
38 586 of the laws of 1998, is amended and a new subsection (b-1) is added
39 to read as follows:

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

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

1 FOUR OF SUBSECTION (B) OF THIS SECTION, THE EXTERNAL APPEAL AGENT SHALL
2 REVIEW MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO CONDITIONS OR
3 DISEASES OF HIGHER PREVALENCE IN THE SAME CLASS OR CATEGORY, DETERMINED
4 BY THE EXTERNAL APPEAL AGENT TO BE COMPARABLE TO THE RARE DISEASE, AS
5 WELL AS MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO THE RARE DISEASE, IN
6 ORDER TO DETERMINE WHETHER THE TREATMENT IS LIKELY TO BENEFIT THE
7 PATIENT, IF THE SPECIFIC HEALTH TREATMENT OR SERVICE RECOMMENDED BY THE
8 HEALTH CARE PROFESSIONAL WOULD NOT OTHERWISE BE EXCLUDED FROM COVERAGE
9 UNDER THE POLICY ON GROUNDS OTHER THAN MEDICAL NECESSITY OR EXPERIMENTAL
10 TREATMENT.

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