

2009-2010 Regular Sessions

I N A S S E M B L Y

(PREFILED)

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Introduced by M. of A. MILLMAN, GOTTFRIED, ROSENTHAL, KELLNER -- Multi-Sponsored by -- M. of A. BRENNAN, BRODSKY, BROOK-KRASNY, CAMARA, CLARK, COOK, DINOWITZ, ESPAILLAT, FIELDS, GLICK, GORDON, GUNTHER, HOOPER, HYER-SPENCER, JACOBS, JAFFEE, JOHN, KOON, V. LOPEZ, MAISEL, MARKEY, MAYERSOHN, ORTIZ, PEOPLES-STOKES, PHEFFER, REILLY, SPANO, STIRPE, WEISENBERG, ZEBROWSKI -- read once and referred 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.

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

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

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

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

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

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

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

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

3 (K) "RARE DISEASE TREATMENT" MEANS A TREATMENT OR SERVICE ADMINISTERED
4 TO AN INSURED 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 6. Section 4905 of the insurance law is amended by adding a new
9 subsection (p) to read as follows:

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

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

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

43 S 8. Item (a) of clause (ii) of subparagraph (B) of paragraph 4 of
44 subsection (b) of section 4914 of the insurance law, as added by chapter
45 586 of the laws of 1998, is amended and a new subsection (b-1) is added
46 to read as follows:

47 (a) that the patient costs of the proposed health service or procedure
48 shall be covered by the health care plan either: when a majority of the
49 panel of reviewers determines, upon review of the applicable medical and
50 scientific evidence (or upon confirmation that the recommended treatment
51 is a clinical trial OR RARE DISEASE TREATMENT), the insured's medical
52 record, and any other pertinent information, that the proposed health
53 service or treatment (including a pharmaceutical product within the
54 meaning of subparagraph (B) of paragraph two of subsection (e) of
55 section four thousand nine hundred of this article) is likely to be more
56 beneficial than any standard treatment or treatments for the insured's

1 life-threatening or disabling condition or disease (or, in the case of a
2 clinical trial OR RARE DISEASE TREATMENT, is likely to benefit the
3 insured in the treatment of the insured's condition or disease); or when
4 a reviewing panel is evenly divided as to a determination concerning
5 coverage of the health service or procedure, or

6 (B-1) FOR EXTERNAL APPEALS REQUESTED IN RELATION TO RARE DISEASE
7 TREATMENT UNDER ITEM (A) OF CLAUSE (II) OF SUBPARAGRAPH (B) OF PARAGRAPH
8 FOUR OF SUBSECTION (B) OF THIS SECTION, THE EXTERNAL APPEAL AGENT SHALL
9 REVIEW MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO CONDITIONS OR
10 DISEASES OF HIGHER PREVALENCE IN THE SAME CLASS OR CATEGORY, DETERMINED
11 BY THE EXTERNAL APPEAL AGENT TO BE COMPARABLE TO THE RARE DISEASE, AS
12 WELL AS MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO THE RARE DISEASE, IN
13 ORDER TO DETERMINE WHETHER THE TREATMENT IS LIKELY TO BENEFIT THE
14 PATIENT, IF THE SPECIFIC HEALTH TREATMENT OR SERVICE RECOMMENDED BY THE
15 HEALTH CARE PROFESSIONAL WOULD NOT OTHERWISE BE EXCLUDED FROM COVERAGE
16 UNDER THE POLICY ON GROUNDS OTHER THAN MEDICAL NECESSITY OR EXPERIMENTAL
17 TREATMENT.

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