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2015-2016 Regular Sessions

I N   A S S E M B L Y

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Introduced by M. of A. TITONE, GOTTFRIED, RODRIGUEZ, GUNTHER, ZEBROWSKI, QUART, PEOPLES-STOKES, MONTESANO, CUSICK, BRINDISI, TEDISCO, WEPRIN, ROSENTHAL, SKOUFIS, ROZIC, JOHNS, JAFFEE, STIRPE, STECK, OTIS, ABINANTI, BARRETT, THIELE, PICHARDO, KEARNS, SANTABARBARA, COLTON, CROUCH, HUNTER, PAULIN, COOK, CYMBROWITZ, JOYNER, GOLDFEDER, LAVINE, CASTORINA, DILAN, McDONALD, MOYA, BRAUNSTEIN, SEAWRIGHT, RAIA, WOERNER, MAGNARELLI, BLAKE, SOLAGES, WALTER -- Multi-Sponsored by -- M. of A. BUCHWALD, CERETTO, CRESPO, DUPREY, ENGLEBRIGHT, FAHY, FRIEND, GALEF, GLICK, HEVESI, KOLB, LENTOL, LUPARDO, LUPINACCI, McDONOUGH, McLAUGHLIN, MURRAY, PERRY, RA, RIVERA, SCHIMEL, SEPULVEDA, TENNEY -- read once and referred to the Committee on Insurance -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- recommitted to the Committee on Insurance in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee -- reported and referred to the Committee on Rules -- Rules Committee discharged, bill amended, ordered reprinted as amended and recommitted to the Committee on Rules

AN ACT to amend the insurance law and the public health law, in relation to expedited utilization review of prescription drugs

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

1     Section 1. Paragraph 10 of subsection (b) of section 3217-a of the  
2 insurance law, as added by chapter 705 of the laws of 1996, is amended  
3 to read as follows:

4     (10) upon written request, provide specific written clinical review  
5 criteria relating to a particular condition or disease INCLUDING CLIN-  
6 ICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETER-  
7 MINATION PURSUANT TO SUBSECTION (C-1), SUBSECTION (C-2) AND SUBSECTION

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

LBD03838-08-6

1 (C-3) OF SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where  
2 appropriate, other clinical information which the insurer might consider  
3 in its utilization review and the insurer may include with the informa-  
4 tion a description of how it will be used in the utilization review  
5 process; provided, however, that to the extent such information is  
6 proprietary to the insurer, the insured or prospective insured shall  
7 only use the information for the purposes of assisting the enrollee or  
8 prospective enrollee in evaluating the covered services provided by the  
9 organization. SUCH CLINICAL REVIEW CRITERIA, AND OTHER CLINICAL INFORMA-  
10 TION SHALL ALSO BE MADE AVAILABLE TO A HEALTH CARE PROFESSIONAL AS  
11 DEFINED IN SUBSECTION (F) OF SECTION FORTY-NINE HUNDRED OF THIS CHAPTER,  
12 ON BEHALF OF AN INSURED AND UPON WRITTEN REQUEST;

13 S 2. Paragraph 10 of subsection (b) of section 4324 of the insurance  
14 law, as added by chapter 705 of the laws of 1996, is amended to read as  
15 follows:

16 (10) upon written request, provide specific written clinical review  
17 criteria relating to a particular condition or disease INCLUDING CLIN-  
18 ICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETER-  
19 MINATION PURSUANT TO SUBSECTION (C-1), SUBSECTION (C-2) AND SUBSECTION  
20 (C-3) OF SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where  
21 appropriate, other clinical information which the corporation might  
22 consider in its utilization review and the corporation may include with  
23 the information a description of how it will be used in the utilization  
24 review process; provided, however, that to the extent such information  
25 is proprietary to the corporation, the subscriber or prospective  
26 subscriber shall only use the information for the purposes of assisting  
27 the subscriber or prospective subscriber in evaluating the covered  
28 services provided by the organization. SUCH CLINICAL REVIEW CRITERIA,  
29 AND OTHER CLINICAL INFORMATION SHALL ALSO BE MADE AVAILABLE TO A HEALTH  
30 CARE PROFESSIONAL AS DEFINED IN SUBSECTION (F) OF SECTION FORTY-NINE  
31 HUNDRED OF THIS CHAPTER, ON BEHALF OF AN INSURED AND UPON WRITTEN  
32 REQUEST;

33 S 3. Section 4900 of the insurance law is amended by adding two new  
34 subsections (g-8) and (g-9) to read as follows:

35 (G-8) "STEP THERAPY PROTOCOL OVERRIDE DETERMINATION" MEANS A DETERMI-  
36 NATION MADE BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBSECTION (I)  
37 OF THIS SECTION TO OVERRIDE A STEP THERAPY PROTOCOL PURSUANT TO  
38 SUBSECTIONS (C-1), (C-2) AND (C-3) OF SECTION FORTY-NINE HUNDRED THREE  
39 OF THIS TITLE GRANTING COVERAGE FOR THE HEALTH CARE PROFESSIONAL'S  
40 SELECTED PRESCRIPTION DRUG OR DRUGS. ANY STEP THERAPY OVERRIDE DETERMI-  
41 NATION AS DEFINED BY THIS SUBSECTION SHALL BE ELIGIBLE FOR APPEAL BY AN  
42 INSURED PURSUANT TO THIS ARTICLE.

43 (G-9) "STEP THERAPY PROTOCOL" MEANS A POLICY, PROTOCOL OR PROGRAM  
44 ESTABLISHED BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBSECTION (I)  
45 OF THIS SECTION THAT ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH  
46 PRESCRIPTION DRUGS FOR A SPECIFIED MEDICAL CONDITION ARE APPROVED FOR A  
47 PARTICULAR INSURED. NOTHING IN THIS CHAPTER SHALL IMPAIR OR PREVENT AN  
48 INSURED FROM HAVING THE RIGHT TO APPEAL PURSUANT TO THIS ARTICLE RELAT-  
49 ING TO THE IMPOSITION OF A STEP THERAPY PROTOCOL.

50 S 4. Subsection (a) of section 4902 of the insurance law is amended by  
51 adding two new paragraphs 10 and 11 to read as follows:

52 10. WHEN ESTABLISHING A STEP THERAPY PROTOCOL, A UTILIZATION REVIEW  
53 AGENT SHALL UTILIZE RECOGNIZED EVIDENCE-BASED AND PEER REVIEWED CLINICAL  
54 REVIEW CRITERIA THAT ALSO TAKES INTO ACCOUNT THE NEEDS OF ATYPICAL  
55 PATIENT POPULATIONS AND DIAGNOSES WHEN ESTABLISHING THE CLINICAL REVIEW  
56 CRITERIA.

11. WHEN CONDUCTING UTILIZATION REVIEW FOR A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION, A UTILIZATION REVIEW AGENT SHALL UTILIZE, IN ADDITION TO ANY OTHER REQUIREMENTS OF THIS ARTICLE, RECOGNIZED EVIDENCE-BASED AND PEER REVIEWED CLINICAL REVIEW CRITERIA THAT IS APPROPRIATE FOR THE INSURED AND THE INSURED'S MEDICAL CONDITION.

S 5. Section 4903 of the insurance law is amended by adding three new subsections (c-1), (c-2) and (c-3) to read as follows:

(C-1) A UTILIZATION REVIEW AGENT SHALL GRANT A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION WITHIN SEVENTY-TWO HOURS OF THE RECEIPT OF INFORMATION THAT INCLUDES SUPPORTING RATIONALE AND DOCUMENTATION FROM A HEALTH CARE PROFESSIONAL WHICH DEMONSTRATES THAT:

(1) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS CONTRAINDICATED OR WILL LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE INSURED;

(2) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS EXPECTED TO BE INEFFECTIVE BASED ON THE KNOWN CLINICAL HISTORY AND CONDITIONS OF THE INSURED AND THE INSURED'S PRESCRIPTION DRUG REGIMEN;

(3) THE INSURED HAS TRIED THE REQUIRED PRESCRIPTION DRUG OR DRUGS WHILE UNDER THEIR CURRENT OR A PREVIOUS HEALTH INSURANCE OR HEALTH BENEFIT PLAN, OR ANOTHER PRESCRIPTION DRUG OR DRUGS IN THE SAME PHARMACOLOGIC CLASS OR WITH THE SAME MECHANISM OF ACTION AND SUCH PRESCRIPTION DRUG OR DRUGS WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS, DIMINISHED EFFECT, OR AN ADVERSE EVENT;

(4) THE INSURED IS STABLE ON A PRESCRIPTION DRUG OR DRUGS SELECTED BY THEIR HEALTH CARE PROFESSIONAL FOR THE MEDICAL CONDITION UNDER CONSIDERATION, PROVIDED THAT THIS SHALL NOT PREVENT A UTILIZATION REVIEW AGENT FROM REQUIRING AN INSURED TO TRY AN AB-RATED GENERIC EQUIVALENT PRIOR TO PROVIDING COVERAGE FOR THE EQUIVALENT BRAND NAME PRESCRIPTION DRUG OR DRUGS; OR

(5) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS NOT IN THE BEST INTEREST OF THE INSURED BECAUSE IT WILL LIKELY CAUSE A SIGNIFICANT BARRIER TO THE INSURED'S ADHERENCE TO OR COMPLIANCE WITH THE INSURED'S PLAN OF CARE, WILL LIKELY WORSEN A COMORBID CONDITION OF THE INSURED, OR WILL LIKELY DECREASE THE COVERED INDIVIDUAL'S ABILITY TO ACHIEVE OR MAINTAIN REASONABLE FUNCTIONAL ABILITY IN PERFORMING DAILY ACTIVITIES.

(C-2) FOR AN INSURED WITH A MEDICAL CONDITION THAT PLACES THE HEALTH OF THE INSURED IN SERIOUS JEOPARDY WITHOUT THE PRESCRIPTION DRUG OR DRUGS PRESCRIBED BY THE INSURED'S HEALTH CARE PROFESSIONAL, THE STEP THERAPY PROTOCOL OVERRIDE DETERMINATION SHALL BE GRANTED WITHIN TWENTY-FOUR HOURS OF THE RECEIPT OF INFORMATION THAT INCLUDES SUPPORTING RATIONALE AND DOCUMENTATION FROM A HEALTH CARE PROFESSIONAL DEMONSTRATING ONE OR MORE OF THE STANDARDS PROVIDED FOR IN SUBSECTION (C-1) OF THIS SECTION.

(C-3) UPON A DETERMINATION THAT THE STEP THERAPY PROTOCOL SHOULD BE OVERRIDDEN, THE HEALTH PLAN SHALL AUTHORIZE IMMEDIATE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE INSURED'S TREATING HEALTH CARE PROFESSIONAL.

S 6. Subsection (g) of section 4903 of the insurance law, as added by chapter 586 of the laws of 1998, is amended to read as follows:

(g) Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section four thousand nine hundred four of this title, PROVIDED, HOWEVER, THAT FAILURE TO MEET SUCH TIME PERIODS FOR A STEP THERAPY PROTOCOL AS DEFINED IN SUBSECTION (G-9) OF SECTION FORTY-NINE HUNDRED OF THIS TITLE OR A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBSECTIONS (C-1),

1 (C-2) AND (C-3) OF THIS SECTION SHALL BE DEEMED TO BE AN OVERRIDE OF THE  
2 STEP THERAPY PROTOCOL.

3 S 7. Paragraph (j) of subdivision 2 of section 4408 of the public  
4 health law, as added by chapter 705 of the laws of 1996, is amended to  
5 read as follows:

6 (j) upon written request, provide specific written clinical review  
7 criteria relating to a particular condition or disease INCLUDING CLIN-  
8 ICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETER-  
9 MINATION PURSUANT TO SUBDIVISIONS THREE-A, THREE-B AND THREE-C OF  
10 SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where appropri-  
11 ate, other clinical information which the organization might consider in  
12 its utilization review and the organization may include with the infor-  
13 mation a description of how it will be used in the utilization review  
14 process; provided, however, that to the extent such information is  
15 proprietary to the organization, the enrollee or prospective enrollee  
16 shall only use the information for the purposes of assisting the enrol-  
17 lee or prospective enrollee in evaluating the covered services provided  
18 by the organization. SUCH CLINICAL REVIEW CRITERIA, AND OTHER CLINICAL  
19 INFORMATION SHALL ALSO BE MADE AVAILABLE TO A HEALTH CARE PROFESSIONAL  
20 AS DEFINED IN SUBDIVISION SIX OF SECTION FORTY-NINE HUNDRED OF THIS  
21 CHAPTER, ON BEHALF OF AN ENROLLEE AND UPON WRITTEN REQUEST;

22 S 8. Section 4900 of the public health law is amended by adding two  
23 new subdivisions 7-f-2 and 7-f-3 to read as follows:

24 7-F-2. "STEP THERAPY PROTOCOL OVERRIDE DETERMINATION" MEANS A DETERMI-  
25 NATION MADE BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBDIVISION NINE  
26 OF THIS SECTION TO OVERRIDE A STEP THERAPY PROTOCOL PURSUANT TO SUBDIVI-  
27 SIONS THREE-A, THREE-B AND THREE-C OF SECTION FORTY-NINE HUNDRED THREE  
28 OF THIS TITLE GRANTING COVERAGE FOR THE HEALTH CARE PROFESSIONAL'S  
29 SELECTED PRESCRIPTION DRUG OR DRUGS. ANY STEP THERAPY PROTOCOL OVERRIDE  
30 DETERMINATION AS DEFINED BY THIS SUBDIVISION SHALL BE ELIGIBLE FOR  
31 APPEAL BY AN ENROLLEE PURSUANT TO THIS ARTICLE.

32 7-F-3. "STEP THERAPY PROTOCOL" MEANS A POLICY, PROTOCOL OR PROGRAM  
33 ESTABLISHED BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBDIVISION NINE  
34 OF THIS SECTION THAT ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH  
35 PRESCRIPTION DRUGS FOR A SPECIFIED MEDICAL CONDITION ARE APPROVED FOR A  
36 PARTICULAR ENROLLEE. NOTHING IN THIS CHAPTER SHALL IMPAIR OR PREVENT AN  
37 INSURED FROM HAVING THE RIGHT TO APPEAL PURSUANT TO THIS ARTICLE RELAT-  
38 ING TO THE IMPOSITION OF A STEP THERAPY PROTOCOL.

39 S 9. Section 4902 of the public health law is amended by adding two  
40 new subdivisions 3 and 4 to read as follows:

41 3. WHEN ESTABLISHING A STEP THERAPY PROTOCOL, A UTILIZATION REVIEW  
42 AGENT SHALL UTILIZE RECOGNIZED EVIDENCE-BASED AND PEER REVIEWED CLINICAL  
43 REVIEW CRITERIA THAT TAKES INTO ACCOUNT THE NEEDS OF ATYPICAL PATIENT  
44 POPULATIONS AND DIAGNOSES AS WELL WHEN ESTABLISHING THE CLINICAL REVIEW  
45 CRITERIA.

46 4. WHEN CONDUCTING UTILIZATION REVIEW FOR A STEP THERAPY PROTOCOL  
47 OVERRIDE DETERMINATION, A UTILIZATION REVIEW AGENT SHALL UTILIZE, IN  
48 ADDITION TO ANY OTHER REQUIREMENTS OF THIS ARTICLE, RECOGNIZED  
49 EVIDENCE-BASED AND PEER REVIEWED CLINICAL REVIEW CRITERIA THAT IS APPRO-  
50 PRIATE FOR THE ENROLLEE AND THE ENROLLEE'S MEDICAL CONDITION.

51 S 10. Section 4903 of the public health law is amended by adding three  
52 new subdivisions 3-a, 3-b and 3-c to read as follows:

53 3-A. A UTILIZATION REVIEW AGENT SHALL GRANT A STEP THERAPY PROTOCOL  
54 OVERRIDE DETERMINATION WITHIN SEVENTY-TWO HOURS OF THE RECEIPT OF INFOR-  
55 MATION THAT INCLUDES SUPPORTING RATIONALE AND DOCUMENTATION FROM A  
56 HEALTH CARE PROFESSIONAL WHICH DEMONSTRATES THAT:

1 (A) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS CONTRAINDICATED, WILL  
2 LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE  
3 ENROLLEE;

4 (B) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS EXPECTED TO BE INEFFECTIVE  
5 BASED ON THE KNOWN CLINICAL HISTORY AND CONDITIONS OF THE ENROLLEE  
6 AND THE ENROLLEE'S PRESCRIPTION DRUG REGIMEN;

7 (C) THE ENROLLEE HAS TRIED THE REQUIRED PRESCRIPTION DRUG OR DRUGS  
8 WHILE UNDER THEIR CURRENT OR A PREVIOUS HEALTH INSURANCE OR HEALTH BENEFIT  
9 PLAN, OR ANOTHER PRESCRIPTION DRUG OR DRUGS IN THE SAME PHARMACOLOGIC  
10 CLASS OR WITH THE SAME MECHANISM OF ACTION AND SUCH PRESCRIPTION DRUG  
11 OR DRUGS WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS,  
12 DIMINISHED EFFECT, OR AN ADVERSE EVENT;

13 (D) THE ENROLLEE IS STABLE ON A PRESCRIPTION DRUG OR DRUGS SELECTED BY  
14 THEIR HEALTH CARE PROFESSIONAL FOR THE MEDICAL CONDITION UNDER CONSIDERATION,  
15 PROVIDED THAT THIS SHALL NOT PREVENT A UTILIZATION REVIEW AGENT  
16 FROM REQUIRING AN INSURED TO TRY AN AB-RATED GENERIC EQUIVALENT PRIOR TO  
17 PROVIDING COVERAGE FOR THE EQUIVALENT BRAND NAME PRESCRIPTION DRUG OR  
18 DRUGS; OR

19 (E) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS NOT IN THE BEST INTEREST  
20 OF THE ENROLLEE BECAUSE IT WILL LIKELY CAUSE A SIGNIFICANT BARRIER  
21 TO THE ENROLLEE'S ADHERENCE TO OR COMPLIANCE WITH THE ENROLLEE'S PLAN OF  
22 CARE, WILL LIKELY WORSEN A COMORBID CONDITION OF THE ENROLLEE, OR WILL  
23 LIKELY DECREASE THE COVERED ENROLLEE'S ABILITY TO ACHIEVE OR MAINTAIN  
24 REASONABLE FUNCTIONAL ABILITY IN PERFORMING DAILY ACTIVITIES.

25 3-B. FOR AN ENROLLEE WITH A MEDICAL CONDITION THAT PLACES THE HEALTH  
26 OF THE INSURED IN SERIOUS JEOPARDY WITHOUT THE PRESCRIPTION DRUG OR  
27 DRUGS PRESCRIBED BY THE INSURED'S HEALTH CARE PROFESSIONAL, THE STEP  
28 THERAPY PROTOCOL OVERRIDE DETERMINATION SHALL BE GRANTED WITHIN TWENTY-  
29 FOUR HOURS OF THE RECEIPT OF INFORMATION THAT INCLUDES SUPPORTING  
30 RATIONALE AND DOCUMENTATION FROM A HEALTH CARE PROFESSIONAL DEMONSTRATING  
31 ONE OR MORE OF THE STANDARDS PROVIDED FOR IN SUBDIVISION THREE-A OF  
32 THIS SECTION.

33 3-C. UPON A DETERMINATION THAT THE STEP THERAPY PROTOCOL SHOULD BE  
34 OVERRIDDEN, THE HEALTH PLAN SHALL AUTHORIZE IMMEDIATE COVERAGE FOR THE  
35 PRESCRIPTION DRUG OR DRUGS PRESCRIBED BY THE ENROLLEE'S TREATING HEALTH  
36 CARE PROFESSIONAL.

37 S 11. Subdivision 7 of section 4903 of the public health law, as added  
38 by chapter 586 of the laws of 1998, is amended to read as follows:

39 7. Failure by the utilization review agent to make a determination  
40 within the time periods prescribed in this section shall be deemed to be  
41 an adverse determination subject to appeal pursuant to section [forty  
42 nine] FORTY-NINE hundred four of this title, PROVIDED, HOWEVER, THAT  
43 FAILURE TO MEET SUCH TIME PERIODS FOR A STEP THERAPY PROTOCOL AS DEFINED  
44 IN SUBDIVISION SEVEN-F-THREE OF SECTION FORTY-NINE HUNDRED OF THIS TITLE  
45 OR A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBDIVISIONS  
46 THREE-A, THREE-B AND THREE-C OF THIS SECTION SHALL BE DEEMED TO BE  
47 AN OVERRIDE OF THE STEP THERAPY PROTOCOL.

48 S 12. This act shall not be construed to prevent: a health care plan  
49 or utilization review agent from requiring a patient to try an AB-rated  
50 generic equivalent prior to providing coverage for the equivalent branded  
51 prescription drug; or a health care provider from prescribing a  
52 prescription drug that is determined to be medically appropriate.

53 S 13. This act shall take effect on January 1, 2017, and shall apply  
54 only to health insurance and health benefit plans delivered, issued for  
55 delivery, or renewed after such date, provided further that effective  
56 immediately the superintendent of financial services is authorized to

1 promulgate such rules and regulations and take any other measures as may  
2 be necessary for the timely implementation of this act.