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

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I N S E N A T E

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Introduced by Sens. YOUNG, AKSHAR, AVELLA, BRESLIN, CARLUCCI, GOLDEN, KAMINSKY, LANZA, LARKIN, LATIMER, LAVALLE, MARCHIONE, PARKER, PERKINS, RIVERA, SAVINO, SQUADRON, VALESKY -- read twice and ordered printed, and when printed to be committed 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 Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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:

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

(10) upon written request, provide specific written clinical review criteria relating to a particular condition or disease INCLUDING CLINICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBSECTION (C-1), SUBSECTION (C-2) AND SUBSECTION (C-3) OF SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where appropriate, other clinical information which the insurer might consider in its utilization review and the insurer may include with the information a description of how it will be used in the utilization review process; provided, however, that to the extent such information is proprietary to the insurer, the insured or prospective insured shall only use the information for the purposes of assisting the enrollee or prospective enrollee in evaluating the covered services provided by the organization. SUCH CLINICAL REVIEW CRITERIA, AND OTHER CLINICAL INFORMATION SHALL ALSO BE MADE AVAILABLE TO A HEALTH CARE PROFESSIONAL AS

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

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DEFINED IN SUBSECTION (F) OF SECTION FORTY-NINE HUNDRED OF THIS CHAPTER, ON BEHALF OF AN INSURED AND UPON WRITTEN REQUEST;

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

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

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

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

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

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

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

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

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

(j) upon written request, provide specific written clinical review criteria relating to a particular condition or disease INCLUDING CLINICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBDIVISIONS THREE-A, THREE-B AND THREE-C OF

SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where appropriate, other clinical information which the organization might consider in its utilization review and the organization may include with the information a description of how it will be used in the utilization review process; provided, however, that to the extent such information is proprietary to the organization, the enrollee or prospective enrollee shall only use the information for the purposes of assisting the enrollee or prospective enrollee in evaluating the covered services provided by the organization. SUCH CLINICAL REVIEW CRITERIA, AND OTHER CLINICAL INFORMATION SHALL ALSO BE MADE AVAILABLE TO A HEALTH CARE PROFESSIONAL AS DEFINED IN SUBDIVISION SIX OF SECTION FORTY-NINE HUNDRED OF THIS CHAPTER, ON BEHALF OF AN ENROLLEE AND UPON WRITTEN REQUEST;

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

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

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

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

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

4. 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 ENROLLEE AND THE ENROLLEE'S MEDICAL CONDITION.

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

3-A. 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:

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

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

(C) THE ENROLLEE 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 PHARMACOLOG-

IC 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;

(D) THE ENROLLEE 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

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

3-B. FOR AN ENROLLEE 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 SUBDIVISION THREE-A OF THIS SECTION.

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

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

7. 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 [forty nine] FORTY-NINE hundred four of this title, PROVIDED, HOWEVER, THAT FAILURE TO MEET SUCH TIME PERIODS FOR A STEP THERAPY PROTOCOL AS DEFINED IN SUBDIVISION SEVEN-F-THREE OF SECTION FORTY-NINE HUNDRED OF THIS TITLE OR A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBDIVISIONS THREE-A, THREE-B AND THREE-C OF THIS SECTION SHALL BE DEEMED TO BE AN OVERRIDE OF THE STEP THERAPY PROTOCOL.

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

S 13. This act shall take effect on January 1, 2017, and shall apply only to health insurance and health benefit plans delivered, issued for delivery, or renewed after such date, provided further that effective immediately the superintendent of financial services is authorized to promulgate such rules and regulations and take any other measures as may be necessary for the timely implementation of this act.