

3419--B

2015-2016 Regular Sessions

I N S E N A T E

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Introduced by Sens. YOUNG, AVELLA, BRESLIN, CARLUCCI, GOLDEN, LANZA, LARKIN, 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

AN ACT to amend the insurance law, in relation to the regulation of step therapy policies

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

- 1 Section 1. Legislative findings. The legislature hereby finds and  
2 declares that:
- 3 (a) Health insurance plans are increasingly making use of step therapy  
4 protocols under which patients are required to try one or more  
5 prescription drugs before coverage is provided for a drug selected by  
6 the patient's health care provider.
- 7 (b) The legislature further finds that such step therapy protocols,  
8 where they are based on well-developed scientific standards and adminis-  
9 tered in a flexible manner that takes into account the individual needs  
10 of patients, can play an important role in controlling health care  
11 costs.
- 12 (c) The legislature further finds that, in some cases, requiring a  
13 patient to follow a step therapy protocol may have adverse and even  
14 dangerous consequences for the patient who may not realize a benefit  
15 from taking a prescription drug or may suffer harm from taking an inap-  
16 propriate drug.
- 17 (d) The legislature further finds that, without uniform policies in  
18 the state for step therapy protocols, patients may not receive the best  
19 and most appropriate treatment.

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

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1 (e) The legislature further finds that it is imperative that step  
2 therapy protocols in the state preserve the health care provider's right  
3 to make treatment decisions in the best interest of the patient.

4 (f) Therefore, the legislature declares it a matter of public interest  
5 that it require health insurers to base step therapy protocols on appro-  
6 priate clinical practice guidelines developed by independent experts  
7 with knowledge of the condition or conditions under consideration; that  
8 patients be exempt from step therapy protocols when inappropriate or  
9 otherwise not in the best interest of the patients; and that patients  
10 have access to a fair, transparent and independent process for request-  
11 ing an exception to a step therapy protocol when appropriate.

12 S 2. The insurance law is amended by adding a new article 33 to read  
13 as follows:

#### 14 ARTICLE 33

##### 15 REGULATION OF STEP THERAPY POLICIES

16 SECTION 3301. DEFINITIONS.

17 3302. CLINICAL REVIEW CRITERIA.

18 3303. EXCEPTIONS PROCESS TRANSPARENCY.

19 3304. COST-SHARING.

20 3305. REGULATIONS.

21 S 3301. DEFINITIONS. AS USED IN THIS ARTICLE:

22 (A) "CLINICAL PRACTICE GUIDELINES" SHALL MEAN A SYSTEMATICALLY DEVEL-  
23 OPED STATEMENT TO ASSIST HEALTH CARE PROVIDER AND PATIENT DECISIONS  
24 ABOUT APPROPRIATE HEALTHCARE FOR SPECIFIC CLINICAL CIRCUMSTANCES AND  
25 CONDITIONS.

26 (B) "CLINICAL REVIEW CRITERIA" SHALL MEAN THE WRITTEN SCREENING PROCE-  
27 DURES, DECISION ABSTRACTS, CLINICAL PROTOCOLS AND PRACTICE GUIDELINES  
28 USED BY AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION TO  
29 DETERMINE THE MEDICAL NECESSITY AND APPROPRIATENESS OF HEALTHCARE  
30 SERVICES.

31 (C) "STEP THERAPY PROTOCOL" SHALL MEAN A PROTOCOL OR PROGRAM THAT  
32 ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH PRESCRIPTION DRUGS FOR A  
33 SPECIFIED MEDICAL CONDITION AND MEDICALLY APPROPRIATE FOR A PARTICULAR  
34 PATIENT ARE COVERED BY AN INSURER OR HEALTH PLAN.

35 (D) "STEP THERAPY OVERRIDE DETERMINATION" SHALL MEAN A DETERMINATION  
36 AS TO WHETHER A STEP THERAPY PROTOCOL SHOULD APPLY IN A PARTICULAR SITU-  
37 ATION, OR WHETHER THE STEP THERAPY PROTOCOL SHOULD BE OVERRIDDEN IN  
38 FAVOR OF IMMEDIATE COVERAGE OF THE HEALTH CARE PROVIDER'S SELECTED  
39 PRESCRIPTION DRUG. THIS DETERMINATION IS BASED ON A REVIEW OF THE  
40 PATIENT'S OR PRESCRIBER'S REQUEST FOR AN OVERRIDE, ALONG WITH SUPPORTING  
41 RATIONALE AND DOCUMENTATION.

42 (E) "UTILIZATION REVIEW ORGANIZATION" SHALL MEAN AN ENTITY THAT  
43 CONDUCTS UTILIZATION REVIEW, OTHER THAN AN INSURER OR HEALTH PLAN  
44 PERFORMING UTILIZATION REVIEW FOR ITS OWN HEALTH BENEFIT PLANS.

45 S 3302. CLINICAL REVIEW CRITERIA. (A) CLINICAL REVIEW CRITERIA USED TO  
46 ESTABLISH A STEP THERAPY PROTOCOL SHALL BE BASED ON CLINICAL PRACTICE  
47 GUIDELINES THAT:

48 (1) RECOMMEND THAT THE PRESCRIPTION DRUGS BE TAKEN IN THE SPECIFIC  
49 SEQUENCE REQUIRED BY THE STEP THERAPY PROTOCOL.

50 (2) ARE DEVELOPED AND ENDORSED BY AN INDEPENDENT, MULTIDISCIPLINARY  
51 PANEL OF EXPERTS NOT AFFILIATED WITH AN INSURER, HEALTH PLAN OR UTILIZA-  
52 TION REVIEW ORGANIZATION.

53 (3) ARE BASED ON HIGH QUALITY STUDIES, RESEARCH, AND MEDICAL PRACTICE.

54 (4) ARE CREATED BY AN EXPLICIT AND TRANSPARENT PROCESS THAT:

55 (A) MINIMIZES BIASES AND CONFLICTS OF INTEREST;

56 (B) EXPLAINS THE RELATIONSHIP BETWEEN TREATMENT OPTIONS AND OUTCOMES;

1 (C) RATES THE QUALITY OF THE EVIDENCE SUPPORTING RECOMMENDATIONS; AND  
2 (D) CONSIDERS RELEVANT PATIENT SUBGROUPS AND PREFERENCES.  
3 (5) ARE CONTINUALLY UPDATED THROUGH A REVIEW OF NEW EVIDENCE AND  
4 RESEARCH.

5 (B) AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION SHALL  
6 CERTIFY ANNUALLY IN RATE FILING DOCUMENTS SUBMITTED TO THE DEPARTMENT OF  
7 FINANCIAL SERVICES THAT THE CLINICAL REVIEW CRITERIA USED IN STEP THERA-  
8 PY PROGRAMS FOR PHARMACEUTICALS MEET THE REQUIREMENTS SET FORTH IN THIS  
9 ACT.

10 (C) PROPOSED CLINICAL REVIEW CRITERIA WILL BE SUBMITTED TO THE DEPART-  
11 MENT OF FINANCIAL SERVICES FOR REVIEW AND MUST RECEIVE APPROVAL OR  
12 ACCREDITATION PRIOR TO IMPLEMENTATION.

13 S 3303. EXCEPTIONS PROCESS TRANSPARENCY. (A) WHEN COVERAGE OF A  
14 PRESCRIPTION DRUG FOR THE TREATMENT OF ANY MEDICAL CONDITION IS  
15 RESTRICTED FOR USE BY AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW  
16 ORGANIZATION THROUGH THE USE OF A STEP THERAPY PROTOCOL, THE PATIENT AND  
17 PRESCRIBING PRACTITIONER SHALL HAVE ACCESS TO A CLEAR AND CONVENIENT  
18 PROCESS TO REQUEST A STEP THERAPY EXCEPTION DETERMINATION. AN INSURER,  
19 HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION MAY USE ITS EXISTING  
20 MEDICAL EXCEPTIONS PROCESS TO SATISFY THIS REQUIREMENT. THE PROCESS  
21 SHALL BE MADE EASILY ACCESSIBLE ON THE INSURER'S, HEALTH PLAN'S, OR  
22 UTILIZATION REVIEW ORGANIZATION'S WEBSITE.

23 (B) A STEP THERAPY OVERRIDE DETERMINATION REQUEST SHALL BE EXPE-  
24 DITIOUSLY GRANTED IF:

25 (1) THE REQUIRED PRESCRIPTION DRUG IS CONTRAINDICATED OR WILL LIKELY  
26 CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE PATIENT.

27 (2) THE REQUIRED PRESCRIPTION DRUG IS EXPECTED TO BE INEFFECTIVE BASED  
28 ON THE KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF THE PATIENT  
29 AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN.

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

36 (4) THE REQUIRED PRESCRIPTION DRUG IS NOT IN THE BEST INTEREST OF THE  
37 PATIENT, BASED ON MEDICAL APPROPRIATENESS.

38 (5) THE PATIENT IS STABLE ON A PRESCRIPTION DRUG SELECTED BY THEIR  
39 HEALTH CARE PROVIDER FOR THE MEDICAL CONDITION UNDER CONSIDERATION.

40 (C) UPON THE GRANTING OF A STEP THERAPY OVERRIDE DETERMINATION, THE  
41 INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION SHALL AUTHORIZE  
42 COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE PATIENT'S TREATING  
43 HEALTHCARE PROVIDER, PROVIDED SUCH PRESCRIPTION DRUG IS A COVERED  
44 PRESCRIPTION DRUG UNDER SUCH POLICY OR CONTRACT.

45 (D) THIS SECTION SHALL NOT BE CONSTRUED TO PREVENT:

46 (1) AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION FROM  
47 REQUIRING A PATIENT TO TRY AN AB-RATED GENERIC EQUIVALENT PRIOR TO  
48 PROVIDING COVERAGE FOR THE EQUIVALENT BRANDED PRESCRIPTION DRUG.

49 (2) A HEALTH CARE PROVIDER FROM PRESCRIBING A PRESCRIPTION DRUG THAT  
50 IS DETERMINED TO BE MEDICALLY APPROPRIATE.

51 (E) EACH HEALTH INSURER SHALL MAINTAIN WRITTEN OR ELECTRONIC RECORDS  
52 AND DATA SUFFICIENT TO DEMONSTRATE COMPLIANCE WITH THE REQUIREMENTS OF  
53 THIS SECTION AND ON AN ANNUAL BASIS SUBMIT TO THE SUPERINTENDENT OF  
54 FINANCIAL SERVICES THE FOLLOWING INFORMATION WITH RESPECT TO REQUESTS  
55 MADE UNDER THIS SECTION:

56 (1) THE TOTAL NUMBER OF REQUESTS RECEIVED;

- 1 (2) THE NUMBER OF REQUESTS APPROVED AND DENIED; AND
- 2 (3) ANY OTHER INFORMATION THE SUPERINTENDENT MAY REQUEST.

3 S 3304. COST-SHARING. (A) NOTWITHSTANDING ANY OTHER PROVISION OF STATE  
4 OR FEDERAL LAW, AN ENTITY LICENSED IN THIS STATE TO SELL A HEALTH INSUR-  
5 ANCE OR HEALTH BENEFITS PLAN DIRECTLY TO A CONSUMER SHALL ENSURE THAT  
6 WHERE STEP THERAPY PROTOCOLS ARE USED TO IMPOSE CLINICAL PREREQUISITES  
7 FOR COVERAGE OF PRESCRIPTION DRUGS, SUCH DRUGS SHALL BE AVAILABLE TO THE  
8 CONSUMER AT THE PREFERRED COST-SHARING LEVEL FOR THE ITEM ONCE THE CLIN-  
9 ICAL PREREQUISITES HAVE BEEN SATISFIED.

10 (B) THIS SECTION SHALL NOT BE CONSTRUED TO PREVENT INSURERS FROM USING  
11 TIERED COPAYMENT STRUCTURES.

12 S 3305. REGULATIONS. NOTWITHSTANDING ANY LAW TO THE CONTRARY, THE  
13 SUPERINTENDENT OF FINANCIAL SERVICES SHALL PROMULGATE ANY REGULATIONS  
14 NECESSARY TO IMPLEMENT THIS ACT.

15 S 3. This act shall take effect on January 1, 2017 and shall apply  
16 only to health insurance and health benefit plans delivered, issued for  
17 delivery, or renewed after such date; provided, further, that effective  
18 immediately the superintendent of financial services is authorized to  
19 promulgate such rules and regulations and take any other measures as may  
20 be necessary for the timely implementation of this act.