

3419--A

2015-2016 Regular Sessions

I N S E N A T E

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Introduced by Sens. YOUNG, AVELLA, BRESLIN, GOLDEN, LANZA, LARKIN, MARCHIONE, PARKER, PERKINS, 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

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

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

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

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

11 ARTICLE 33

12 REGULATION OF STEP THERAPY POLICIES

13 SECTION 3301. DEFINITIONS.

14 3302. CLINICAL REVIEW CRITERIA.

15 3303. EXCEPTIONS PROCESS TRANSPARENCY.

16 3304. COST-SHARING.

17 3305. REGULATIONS.

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

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

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

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

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

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

42 S 3302. CLINICAL REVIEW CRITERIA. (A) CLINICAL REVIEW CRITERIA USED TO
43 ESTABLISH A STEP THERAPY PROTOCOL SHALL BE BASED ON CLINICAL PRACTICE
44 GUIDELINES THAT:

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

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

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

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

52 (A) MINIMIZES BIASES AND CONFLICTS OF INTEREST;

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

54 (C) RATES THE QUALITY OF THE EVIDENCE SUPPORTING RECOMMENDATIONS; AND

55 (D) CONSIDERS RELEVANT PATIENT SUBGROUPS AND PREFERENCES.

1 (5) ARE CONTINUALLY UPDATED THROUGH A REVIEW OF NEW EVIDENCE AND
2 RESEARCH.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

54 (1) THE TOTAL NUMBER OF REQUESTS RECEIVED;

55 (2) THE NUMBER OF REQUESTS APPROVED AND DENIED; AND

56 (3) ANY OTHER INFORMATION THE SUPERINTENDENT MAY REQUEST.

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

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

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

13 S 3. This act shall take effect on January 1, 2016 and shall apply
14 only to health insurance and health benefit plans delivered, issued for
15 delivery, or renewed after such date; provided, further, that effective
16 immediately the superintendent of financial services is authorized to
17 promulgate such rules and regulations and take any other measures as may
18 be necessary for the timely implementation of this act.