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I N A S S E M B L Y

February 24, 2012

Introduced by M. of A. TITONE -- read once and referred to the Committee
on Insurance

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

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

1 Section 1. The insurance law is amended by adding a new article 33 to
2 read as follows:

3 ARTICLE 33

4 REGULATION OF STEP THERAPY AND
5 FIRST FAIL POLICIES

6 SECTION 3301. DEFINITIONS.

7 3302. PRESCRIPTION DRUG RESTRICTION OVERRIDES.

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

9 (A) "INSURER" SHALL MEAN ANY PERSON OR ENTITY WHO OFFERS A POLICY OF
10 ACCIDENT AND/OR HEALTH INSURANCE PURSUANT TO SECTION THREE THOUSAND TWO
11 HUNDRED SIXTEEN, THREE THOUSAND TWO HUNDRED TWENTY-ONE, OR FOUR THOUSAND
12 THREE HUNDRED THREE OF THIS CHAPTER OR ARTICLE FORTY-FOUR OF THE PUBLIC
13 HEALTH LAW, INCLUDING MANAGED CARE PROVIDERS AS DEFINED IN SECTION THREE
14 HUNDRED SIXTY-FOUR-J OF THE SOCIAL SERVICES LAW;

15 (B) "PHARMACY BENEFIT MANAGEMENT" OR "PBM" SHALL MEAN THE SERVICE
16 PROVIDED TO AN INSURER, DIRECTLY OR THROUGH ANOTHER ENTITY; INCLUDING
17 THE PROCUREMENT OF PRESCRIPTION DRUGS TO BE DISPENSED TO COVERED
18 PERSONS, OR THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG BENE-
19 FITS INCLUDING, BUT NOT LIMITED TO, ANY OF THE FOLLOWING:

20 (1) A MAIL ORDER PHARMACY;

21 (2) CLAIMS PROCESSING, RETAIL NETWORK MANAGEMENT AND PAYMENT OF CLAIMS
22 TO PHARMACIES FOR DISPENSING PRESCRIPTION DRUGS;

23 (3) CLINICAL OR OTHER FORMULARY, OR PREFERRED DRUG LIST DEVELOPMENT OR
24 MANAGEMENT;

25 (4) NEGOTIATION OR ADMINISTRATION OF REBATES, DISCOUNTS, PAYMENT
26 DIFFERENTIALS OR OTHER INCENTIVES FOR THE INCLUSION OF PARTICULAR
27 PRESCRIPTION DRUGS IN A PARTICULAR CATEGORY OR TO PROMOTE THE PURCHASE
28 OF PARTICULAR PRESCRIPTION DRUGS;

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

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1 (5) PATIENT COMPLIANCE, THERAPEUTIC INTERVENTION AND GENERIC SUBSTI-
2 TUTION PROGRAMS; AND

3 (6) DISEASE MANAGEMENT.

4 S 3302. PRESCRIPTION DRUG RESTRICTION OVERRIDES. (A) WHEN MEDICATIONS
5 FOR THE TREATMENT OF ANY MEDICAL CONDITION ARE RESTRICTED FOR USE BY AN
6 INSURER OR PBM BY A STEP THERAPY OR FAIL FIRST PROTOCOL, A PRESCRIBER
7 SHALL HAVE ACCESS TO A CLEAR AND CONVENIENT PROCESS TO OVERRIDE SUCH
8 RESTRICTIONS FROM THE INSURER AND MAY EXPEDITIOUSLY OVERRIDE SUCH
9 RESTRICTION IF:

10 (1) SUCH PRESCRIBER, IN HIS OR HER PROFESSIONAL JUDGMENT, BELIEVES
11 THAT THE PREFERRED TREATMENT BY THE INSURER OR THE PBM HAS BEEN INEFFECT-
12 TIVE IN THE TREATMENT OF THE COVERED PERSON'S DISEASE OR MEDICAL CONDI-
13 TION; OR

14 (2) BASED ON SOUND CLINICAL EVIDENCE AND MEDICAL AND SCIENTIFIC
15 EVIDENCE:

16 (A) SUCH PRESCRIBER, IN HIS OR HER PROFESSIONAL JUDGMENT, BELIEVES
17 THAT THE PREFERRED TREATMENT IS EXPECTED TO BE INEFFECTIVE BASED ON THE
18 KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF THE COVERED PERSON
19 AND KNOWN CHARACTERISTICS OF THE DRUG REGIMEN, AND IS LIKELY TO BE INEF-
20 FECTIVE OR ADVERSELY AFFECT THE DRUG'S EFFECTIVENESS OR PATIENT COMPLI-
21 ANCE; OR

22 (B) SUCH PRESCRIBER, IN HIS OR HER PROFESSIONAL JUDGMENT, BELIEVES
23 THAT THE PREFERRED TREATMENT HAS CAUSED OR IS LIKELY TO CAUSE AN ADVERSE
24 REACTION OR OTHER HARM TO THE COVERED PERSON.

25 (B) THE DURATION OF ANY STEP THERAPY OR FAIL FIRST PROTOCOL SHALL NOT
26 BE LONGER THAN EITHER (1) THE PERIOD DEEMED NECESSARY BY THE PRESCRIBING
27 PHYSICIAN OR HEALTH CARE PROFESSIONAL TO DETERMINE THE TREATMENT'S CLIN-
28 ICAL EFFECTIVENESS, OR (2) A PERIOD OF THIRTY DAYS.

29 (C) FOR MEDICATIONS WITH NO GENERIC EQUIVALENT AND FOR WHICH THE PRES-
30 CRIBER IN HIS OR HER CLINICAL JUDGMENT BELIEVES THAT NO APPROPRIATE
31 THERAPEUTIC ALTERNATIVE IS AVAILABLE, AN INSURER OR PBM SHALL PROVIDE
32 ACCESS TO UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) LABELED MEDI-
33 CATIONS WITHOUT RESTRICTION TO TREAT SUCH MEDICAL CONDITIONS FOR WHICH
34 AN FDA LABELED MEDICATION IS AVAILABLE.

35 (D) NOTHING IN THIS SECTION SHALL REQUIRE COVERAGE FOR AN ADDITIONAL
36 CONDITION NOT ALREADY COVERED BY THE POLICY OR CONTRACT, OR WHICH IS NOT
37 OTHERWISE COVERED BY LAW.

38 S 2. This act shall take effect on the one hundred twentieth day after
39 it shall have become a law.