

5214

2013-2014 Regular Sessions

I N A S S E M B L Y

February 21, 2013

Introduced by M. of A. TITONE -- Multi-Sponsored by -- M. of A. BARRON
-- 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;

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

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

(5) PATIENT COMPLIANCE, THERAPEUTIC INTERVENTION AND GENERIC SUBSTITUTION PROGRAMS; AND

(6) DISEASE MANAGEMENT.

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

(1) SUCH PRESCRIBER, IN HIS OR HER PROFESSIONAL JUDGMENT, BELIEVES THAT THE PREFERRED TREATMENT BY THE INSURER OR THE PBM HAS BEEN INEFFECTIVE IN THE TREATMENT OF THE COVERED PERSON'S DISEASE OR MEDICAL CONDITION; OR

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

(A) SUCH PRESCRIBER, IN HIS OR HER PROFESSIONAL JUDGMENT, BELIEVES THAT THE PREFERRED TREATMENT IS EXPECTED TO BE INEFFECTIVE BASED ON THE KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF THE COVERED PERSON AND KNOWN CHARACTERISTICS OF THE DRUG REGIMEN, AND IS LIKELY TO BE INEFFECTIVE OR ADVERSELY AFFECT THE DRUG'S EFFECTIVENESS OR PATIENT COMPLIANCE; OR

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

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

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

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

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