

5110

2011-2012 Regular Sessions

I N   S E N A T E

May 3, 2011

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Introduced by Sen. YOUNG -- read twice and ordered printed, and when  
printed to be committed to the Committee on Insurance

AN ACT to amend the insurance law, in relation to the prohibition on  
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                         PROHIBITION ON FIRST FAIL POLICIES AND  
5                         UNAUTHORIZED THERAPEUTIC SUBSTITUTION

6     SECTION 3301. DEFINITIONS.

7             3302. PRESCRIPTION DRUG DENIALS.

8             3303. SWITCH COMMUNICATIONS/CONSUMER RIGHT TO KNOW.

9             3304. PENALTIES.

10            3305. PRESCRIPTION DRUG RESTRICTION OVERRIDES.

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

12     (A) "INSURER" SHALL MEAN ANY PERSON OR ENTITY WHO OFFERS A POLICY OF  
13     ACCIDENT AND/OR HEALTH INSURANCE PURSUANT TO SECTION THREE THOUSAND TWO  
14     HUNDRED SIXTEEN, THREE THOUSAND TWO HUNDRED TWENTY-ONE, OR FOUR THOUSAND  
15     THREE HUNDRED THREE OF THIS CHAPTER OR ARTICLE FORTY-FOUR OF THE PUBLIC  
16     HEALTH LAW; EXCEPT WHEN SUCH HEALTH CARE SERVICES ARE PROVIDED, DELIV-  
17     ERED, ARRANGED FOR, PAID FOR, OR REIMBURSED BY ANY STATE, DEPARTMENT OR  
18     AGENCY;

19     (B) "PHARMACY BENEFITS MANAGER" OR "PBM", MEANS A PERSON OR ENTITY  
20     OTHER THAN A PHARMACY OR PHARMACIST ACTING AS AN ADMINISTRATOR IN  
21     CONNECTION WITH PHARMACY BENEFITS;

22     (C) "SWITCH COMMUNICATION", MEANS A WRITTEN COMMUNICATION FROM ANY  
23     INSURER OR PBM TO A PATIENT OR THE PATIENT'S PHYSICIAN THAT RECOMMENDS A  
24     PATIENT'S MEDICATION BE SWITCHED BY THE ORIGINAL PRESCRIBING HEALTH CARE

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

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1 PROFESSIONAL TO A DIFFERENT MEDICATION THAN THE MEDICATION ORIGINALLY  
2 PRESCRIBED BY THE PRESCRIBING HEALTH CARE PROFESSIONAL.

3 (D) "GENERIC EQUIVALENT" MEANS A DRUG THAT IS THE SAME CHEMICAL  
4 COMPOUND AS ANOTHER DRUG AND IS THE SAME DOSAGE FORM, STRENGTH, ROUTE OF  
5 ADMINISTRATION, AND INTENDED USE, AND IS LISTED AS EQUIVALENT IN FDA'S  
6 APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE  
7 BOOK).

8 (E) "THERAPEUTIC SUBSTITUTION" MEANS THE DISPENSING OF A CHEMICALLY  
9 DIFFERENT DRUG IN THE PLACE OF THE DRUG ORIGINALLY PRESCRIBED BY THE  
10 PATIENT'S PHYSICIAN OR OTHER PRESCRIBING HEALTH CARE PROFESSIONAL,  
11 INCLUDING BIOLOGICS AND PLASMA-DERIVED THERAPIES. THERAPEUTIC SUBSTI-  
12 TUTION DOES NOT INCLUDE SUBSTITUTION OF A GENERIC EQUIVALENT.

13 S 3302. PRESCRIPTION DRUG DENIALS. (A) A POLICY OF ACCIDENT AND/OR  
14 HEALTH INSURANCE THAT COVERS PRESCRIPTION DRUGS SHALL NOT LIMIT, REDUCE,  
15 OR DENY COVERAGE FOR ANY DRUG IF, PRIOR TO THE LIMITATION, REDUCTION, OR  
16 DENIAL OF COVERAGE:

17 (1) ANY INSURED WAS USING THE DRUG;

18 (2) SUCH INSURED OR INSUREDS WERE COVERED UNDER THE POLICY; AND

19 (3) THE DRUG WAS COVERED UNDER THE POLICY FOR SUCH INSURED INDIVIDUAL  
20 OR INDIVIDUALS.

21 (B) A LIMITATION, REDUCTION, OR DENIAL OF COVERAGE INCLUDES REMOVING A  
22 DRUG FROM THE FORMULARY OR OTHER DRUG LIST, IMPOSING NEW PRIOR AUTHORI-  
23 ZATION OR OTHER UTILIZATION MANAGEMENT TOOLS, OR PLACING THE DRUG ON A  
24 FORMULARY TIER THAT INCREASES THE PATIENT'S COST-SHARING OBLIGATIONS OR  
25 OTHERWISE INCREASES THE PATIENT'S COST-SHARING OBLIGATIONS.

26 (C) NOTHING IN THIS SECTION SHALL PROHIBIT AN INSURER FROM MAKING  
27 UNIFORM CHANGES IN ITS BENEFIT DESIGN THAT APPLY TO ALL COVERED DRUGS,  
28 UNIFORMLY REMOVING A DRUG FROM THE FORMULARY LIST FOR ALL INSUREDS, OR  
29 INCREASING COST-SHARING OBLIGATIONS MERELY DUE TO A PERCENTAGE COINSU-  
30 RANCE PAYMENT THAT NECESSARILY INCREASES WITH AN INCREASE IN THE UNDER-  
31 LYING DRUG PRICES.

32 (D) NO THERAPEUTIC SUBSTITUTION OF A MEDICATION BY ANYONE AUTHORIZED  
33 TO DISPENSE MEDICATIONS FOR SELF OR HOME ADMINISTRATION BY A CONSUMER  
34 SHALL BE ALLOWED WITHOUT THE EXPRESS AUTHORIZATION OF THE ORIGINAL  
35 PRESCRIBING PHYSICIAN OR HEALTH CARE PROFESSIONAL AND NOTICE TO THE  
36 PATIENT AND THE POLICY SPONSOR AS PROVIDED FOR IN SECTION THIRTY-THREE  
37 HUNDRED THREE OF THIS ARTICLE. PRIOR TO MAKING A THERAPEUTIC SUBSTI-  
38 TUTION IN A PATIENT'S PRESCRIPTION INCLUDING BUT NOT LIMITED TO CHANGES  
39 IN PRODUCT SELECTION AND CHANGES IN DOSAGE, THE DISPENSING PHARMACIST  
40 SHALL:

41 (1) VERBALLY REQUEST THE PATIENT TO AGREE TO A CHANGE TO THE  
42 PRESCRIPTION, AND EXPLAIN THAT THE CHANGE CANNOT BE MADE UNLESS BOTH THE  
43 PATIENT AND THE PRESCRIBING PHYSICIAN (OR OTHER PRESCRIBING HEALTH CARE  
44 PROFESSIONAL) EXPRESSLY AGREE TO THE CHANGE;

45 (2) VERBALLY DESCRIBE THE PROPOSED CHANGE THAT WOULD BE MADE TO THE  
46 PRESCRIPTION, INCLUDING CLEARLY IDENTIFYING THE ORIGINALLY PRESCRIBED  
47 MEDICATION AND THE MEDICATION THAT WOULD BE SUBSTITUTED FOR THE  
48 ORIGINALLY PRESCRIBED MEDICATION; AND

49 (3) VERBALLY INFORM THE PATIENT OF THE IMPACT, IF ANY, ON THE  
50 PATIENT'S OUT-OF-POCKET COST.

51 S 3303. SWITCH COMMUNICATIONS/CONSUMER RIGHT TO KNOW. (A) ANY TIME A  
52 PATIENT'S PRESCRIBED MEDICATION IS RECOMMENDED TO BE SWITCHED TO A MEDI-  
53 CATION OTHER THAN THAT ORIGINALLY PRESCRIBED BY THE PRESCRIBING PRACTI-  
54 TIONER, A SWITCH COMMUNICATION SHALL BE SENT TO:

(1) THE PATIENT AND SHALL PROVIDE INFORMATION ABOUT WHY THE SWITCH IS PROPOSED AND THE PATIENT'S RIGHTS FOR REFUSING THE RECOMMENDED CHANGE IN TREATMENT; AND

(2) THE POLICY SPONSOR AND SHALL INFORM SUCH SPONSOR OF THE PHARMACEUTICAL WHOLESALE ACQUISITION COST, SHOWN IN CURRENCY FORM, OF THE RECOMMENDED MEDICATION AND THE WHOLESALE ACQUISITION COST, SHOWN IN CURRENCY FORM, OF THE ORIGINALLY PRESCRIBED MEDICATION.

(B) SUCH SWITCH COMMUNICATION SHALL:

(1) CLEARLY IDENTIFY THE ORIGINALLY PRESCRIBED MEDICATION AND THE MEDICATION TO WHICH IT HAS BEEN PROPOSED THAT THE PATIENT SHOULD BE SWITCHED;

(2) PROVIDE INFORMATION WHICH IS TRUTHFUL, ACCURATE, AND NOT MISLEADING, WITH APPROPRIATE FAIR BALANCE, CONSISTENT WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR MEDICATIONS;

(3) INCLUDE CURRENT APPROVED PRODUCT LABELING AND INFORMATION ABOUT RISKS ASSOCIATED WITH THE RECOMMENDED MEDICATION;

(4) CLEARLY ACKNOWLEDGE THAT NO THERAPEUTIC SUBSTITUTION SHALL BE ALLOWED WITHOUT THE EXPRESS AUTHORIZATION OF THE ORIGINAL PRESCRIBING PHYSICIAN OR OTHER ORIGINAL PRESCRIBING HEALTH CARE PROFESSIONAL;

(5) ADVISE THE PATIENT OF HIS OR HER RIGHTS TO DISCUSS THE PROPOSED CHANGE IN TREATMENT BEFORE SUCH A SWITCH TAKES PLACE, INCLUDING A DISCUSSION WITH THE PATIENT'S PRESCRIBING PRACTITIONER, THE FILING OF A GRIEVANCE WITH THE INSURER TO PREVENT THE SWITCH IF SUCH A SWITCH IS BASED ON A FINANCIAL INCENTIVE AND THE FILING OF A GRIEVANCE WITH THE DEPARTMENT; AND

(6) EXPLAIN ANY COST-SHARING CHANGES FOR WHICH THE PATIENT IS RESPONSIBLE.

(C) A COPY OF ANY SWITCH COMMUNICATION SENT TO A PATIENT SHALL ALSO BE SENT TO THE PRESCRIBING PRACTITIONER.

(D) HEALTH INSURANCE PAYERS, INCLUDING EMPLOYERS RESPONSIBLE FOR PAYING THE HEALTH CARE PREMIUM OR PORTIONS THEREOF, SHALL BE NOTIFIED OF THERAPEUTIC SUBSTITUTIONS AMONG POLICY PARTICIPANTS AND OF ANY THERAPEUTIC SUBSTITUTION PROGRAMS ADOPTED BY HEALTH PLANS AND PHARMACY BENEFIT MANAGERS IN ANY PLAN OFFERED BY SUCH PREMIUM PAYER OR EMPLOYER.

(E) THE DEPARTMENT SHALL CREATE ONE FORM FOR INSURERS AND PHARMACY BENEFIT MANAGERS TO USE IN SWITCH COMMUNICATIONS TO PATIENTS, PRESCRIBING PRACTITIONERS, AND HEALTH INSURANCE PAYERS INCLUDING EMPLOYERS.

(F) THE DEPARTMENT SHALL PROMULGATE RULES GOVERNING SWITCH COMMUNICATIONS. SUCH RULES SHALL INCLUDE, BUT NOT BE LIMITED TO THE FOLLOWING:

(1) PROCEDURES FOR VERIFYING THE ACCURACY OF ANY SWITCH COMMUNICATIONS FROM POLICIES OF ACCIDENT AND/OR HEALTH INSURANCE AND PHARMACY BENEFIT MANAGERS TO ENSURE THAT SUCH SWITCH COMMUNICATIONS ARE TRUTHFUL, ACCURATE, AND NOT MISLEADING BASED ON COST TO THE PATIENT AND POLICY SPONSOR, THE PRODUCT PACKAGE LABELING, MEDICAL COMPENDIA RECOGNIZED BY THE DRUG UTILIZATION REVIEW BOARD, AND PEER-REVIEWED MEDICAL LITERATURE, WITH APPROPRIATE REFERENCES PROVIDED;

(2) EXCEPT FOR A SUBSTITUTION DUE TO THE FOOD AND DRUG ADMINISTRATION'S WITHDRAWAL OF A DRUG FOR PRESCRIPTION, A REQUIREMENT THAT ALL SWITCH COMMUNICATIONS BEAR A PROMINENT LEGEND ON THE FIRST PAGE THAT STATES: "THIS IS NOT A PRODUCT SAFETY NOTICE. THIS IS A PROMOTIONAL ANNOUNCEMENT FROM YOUR HEALTH CARE INSURER OR PHARMACY BENEFITS MANAGER ABOUT ONE OF YOUR CURRENT PRESCRIBED MEDICATIONS.";

(3) A REQUIREMENT THAT, THE NOTIFICATION OF REQUEST FOR MEDICATION CHANGE (I) EXPRESSLY STATES THAT THE CHANGE INVOLVES A THERAPEUTIC SUBSTITUTION, NOT A GENERIC SUBSTITUTION; (II) EXPLAIN THE DIFFERENCE BETWEEN THERAPEUTIC SUBSTITUTION AND GENERIC SUBSTITUTION; AND (III)

1 PROVIDE A TRUTHFUL, FAIR, AND BALANCED EXPLANATION REGARDING THE POTEN-  
2 TIAL, RAMIFICATIONS OF THE THERAPEUTIC SUBSTITUTION, INCLUDING BUT NOT  
3 LIMITED TO, THAT MEDICATIONS IN THE SAME THERAPEUTIC CLASS ARE ASSOCI-  
4 ATED WITH DIFFERENT RISKS AND BENEFITS AND MAY WORK DIFFERENTLY IN  
5 DIFFERENT PATIENTS.

6 S 3304. PENALTIES. (A) ISSUING OR DELIVERING OR CAUSING TO BE ISSUED  
7 OR DELIVERED A SWITCH COMMUNICATION THAT HAS NOT BEEN APPROVED AND IS  
8 NOT IN COMPLIANCE WITH THE REQUIREMENTS OF SECTION THREE THOUSAND THREE  
9 HUNDRED THREE OF THIS ARTICLE IS PUNISHABLE BY A FINE NOT TO EXCEED  
10 TWENTY-FIVE THOUSAND DOLLARS.

11 (B) PROVIDING A MISREPRESENTATION OR FALSE STATEMENT IN A SWITCH  
12 COMMUNICATION UNDER SECTION THREE THOUSAND THREE HUNDRED THREE OF THIS  
13 ARTICLE IS PUNISHABLE BY A FINE NOT TO EXCEED TWENTY-FIVE THOUSAND  
14 DOLLARS.

15 (C) ANY OTHER MATERIAL VIOLATION OF SECTION THREE THOUSAND THREE  
16 HUNDRED THREE OF THIS ARTICLE IS PUNISHABLE BY A FINE NOT TO EXCEED  
17 TWENTY-FIVE THOUSAND DOLLARS.

18 S 3305. PRESCRIPTION DRUG RESTRICTION OVERRIDES. (A) WHEN MEDICATIONS  
19 FOR THE TREATMENT OF ANY MEDICAL CONDITION ARE RESTRICTED FOR USE BY AN  
20 INSURER OR PBM BY A STEP THERAPY OR FAIL FIRST PROTOCOL, A PRESCRIBER  
21 SHALL HAVE ACCESS TO A CLEAR AND CONVENIENT PROCESS TO OVERRIDE SUCH  
22 RESTRICTIONS FROM THE INSURER AND MAY EXPEDITIOUSLY OVERRIDE SUCH  
23 RESTRICTION IF:

24 (1) THE PREFERRED TREATMENT BY THE INSURER OR THE PBM HAS BEEN INEF-  
25 FECTIVE IN THE TREATMENT OF THE COVERED PERSON'S DISEASE OR MEDICAL  
26 CONDITION; OR

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

29 (A) THE PREFERRED TREATMENT IS EXPECTED TO BE INEFFECTIVE BASED ON THE  
30 KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF THE COVERED PERSON  
31 AND KNOWN CHARACTERISTICS OF THE DRUG REGIMEN, AND IS LIKELY TO BE INEF-  
32 FECTIVE OR ADVERSELY AFFECT THE DRUG'S EFFECTIVENESS OR PATIENT COMPLI-  
33 ANCE; OR

34 (B) THE PREFERRED TREATMENT HAS CAUSED OR IS LIKELY TO CAUSE AN  
35 ADVERSE REACTION OR OTHER HARM TO THE COVERED PERSON.

36 (B) THE DURATION OF ANY STEP THERAPY OR FAIL FIRST PROTOCOL SHALL NOT  
37 BE LONGER THAN THE PERIOD DEEMED NECESSARY BY THE PRESCRIBING PHYSICIAN  
38 OR HEALTH CARE PROFESSIONAL TO DETERMINE THE TREATMENT'S CLINICAL EFFEC-  
39 TIVENESS OR A PERIOD OF FOURTEEN DAYS.

40 (C) FOR MEDICATIONS WITH NO GENERIC EQUIVALENT AND FOR WHICH THE  
41 PRESCRIBING PHYSICIAN IN THEIR CLINICAL JUDGMENT FEELS THAT NO APPROPRI-  
42 ATE THERAPEUTIC ALTERNATIVE IS AVAILABLE AN INSURER OR PBM SHALL PROVIDE  
43 ACCESS TO UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) LABELED MEDI-  
44 CATIONS WITHOUT RESTRICTION TO TREAT SUCH MEDICAL CONDITIONS FOR WHICH  
45 AN FDA LABELED MEDICATION IS AVAILABLE.

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

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