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I N S E N A T E

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Introduced by Sens. YOUNG, ADDABBO -- 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 THREE THOUSAND
37 THREE HUNDRED THREE OF THIS ARTICLE. PRIOR TO MAKING A THERAPEUTIC
38 SUBSTITUTION IN A PATIENT'S PRESCRIPTION INCLUDING BUT NOT LIMITED TO
39 CHANGES IN PRODUCT SELECTION AND CHANGES IN DOSAGE, THE DISPENSING PHAR-
40 MACIST 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.