

# STATE OF NEW YORK

7018

2017-2018 Regular Sessions

## IN ASSEMBLY

March 29, 2017

Introduced by M. of A. TITONE, JAFFEE -- Multi-Sponsored by -- M. of A. HIKIND, PRETLOW, SIMOTAS -- read once and referred 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 Assembly, do enact as follows:

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

### ARTICLE 33

#### PROHIBITION ON FIRST FAIL POLICIES AND UNAUTHORIZED THERAPEUTIC SUBSTITUTION

##### Section 3301. Definitions.

3 3302. Prescription drug denials.

4 3303. Switch communications/consumer right to know.

5 3304. Penalties.

6 3305. Prescription drug restriction overrides.

##### § 3301. Definitions. As used in this article:

7 (a) "Insurer" shall mean any person or entity who offers a policy of  
8 accident and/or health insurance pursuant to section three thousand two  
9 hundred sixteen, three thousand two hundred twenty-one, or four thousand  
10 three hundred three of this chapter or article forty-four of the public  
11 health law; except when such health care services are provided, deliv-  
12 ered, arranged for, paid for, or reimbursed by any state, department or  
13 agency;

14 (b) "Pharmacy benefits manager" or "PBM", means a person or entity  
15 other than a pharmacy or pharmacist acting as an administrator in  
16 connection with pharmacy benefits;

17 (c) "Switch communication", means a written communication from any  
18 insurer or PBM to a patient or the patient's physician that recommends a  
19 patient's medication be switched by the original prescribing health care  
20

21 EXPLANATION--Matter in italics (underscored) is new; matter in brackets  
22 [-] 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 § 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 § 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 (1) The patient and shall provide information about why the switch is  
2 proposed and the patient's rights for refusing the recommended change in  
3 treatment; and

4 (2) The policy sponsor and shall inform such sponsor of the pharmaceu-  
5 tical wholesale acquisition cost, shown in currency form, of the recom-  
6 mended medication and the wholesale acquisition cost, shown in currency  
7 form, of the originally prescribed medication.

8 (b) Such switch communication shall:

9 (1) Clearly identify the originally prescribed medication and the  
10 medication to which it has been proposed that the patient should be  
11 switched;

12 (2) Provide information which is truthful, accurate, and not mislead-  
13 ing, with appropriate fair balance, consistent with the United States  
14 Food and Drug Administration for medications;

15 (3) Include current approved product labeling and information about  
16 risks associated with the recommended medication;

17 (4) Clearly acknowledge that no therapeutic substitution shall be  
18 allowed without the express authorization of the original prescribing  
19 physician or other original prescribing health care professional;

20 (5) Advise the patient of his or her rights to discuss the proposed  
21 change in treatment before such a switch takes place, including a  
22 discussion with the patient's prescribing practitioner, the filing of a  
23 grievance with the insurer to prevent the switch if such a switch is  
24 based on a financial incentive and the filing of a grievance with the  
25 department; and

26 (6) Explain any cost-sharing changes for which the patient is respon-  
27 sible.

28 (c) A copy of any switch communication sent to a patient shall also be  
29 sent to the prescribing practitioner.

30 (d) Health insurance payers, including employers responsible for  
31 paying the health care premium or portions thereof, shall be notified of  
32 therapeutic substitutions among policy participants and of any therapeu-  
33 tic substitution programs adopted by health plans and pharmacy benefit  
34 managers in any plan offered by such premium payer or employer.

35 (e) The department shall create one form for insurers and pharmacy  
36 benefit managers to use in switch communications to patients, prescrib-  
37 ing practitioners, and health insurance payers including employers.

38 (f) The department shall promulgate rules governing switch communi-  
39 cations. Such rules shall include, but not be limited to the following:

40 (1) Procedures for verifying the accuracy of any switch communications  
41 from policies of accident and/or health insurance and pharmacy benefit  
42 managers to ensure that such switch communications are truthful, accu-  
43 rate, and not misleading based on cost to the patient and policy spon-  
44 sor, the product package labeling, medical compendia recognized by the  
45 drug utilization review board, and peer-reviewed medical literature,  
46 with appropriate references provided;

47 (2) Except for a substitution due to the Food and Drug Adminis-  
48 tration's withdrawal of a drug for prescription, a requirement that all  
49 switch communications bear a prominent legend on the first page that  
50 states: "This is not a product safety notice. This is a promotional  
51 announcement from your health care insurer or pharmacy benefits manager  
52 about one of your current prescribed medications.";

53 (3) A requirement that, the notification of request for medication  
54 change (i) expressly states that the change involves a therapeutic  
55 substitution, not a generic substitution; (ii) explain the difference  
56 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 § 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 § 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 § 2. This act shall take effect on the one hundred twentieth day after  
50 it shall have become a law.