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:

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

ARTICLE 33

PROHIBITION ON FIRST FAIL POLICIES AND UNAUTHORIZED THERAPEUTIC SUBSTITUTION

Section 3301. Definitions.
3302. Prescription drug denials.
3303. Switch communications/consumer right to know.
3304. Penalties.
3305. Prescription drug restriction overrides.

§ 3301. Definitions. As used in this article:

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

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

(c) "Switch communication", means a written communication from any insurer or PBM to a patient or the patient's physician that recommends a 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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professional to a different medication than the medication originally prescribed by the prescribing health care professional.

(d) "Generic equivalent" means a drug that is the same chemical compound as another drug and is the same dosage form, strength, route of administration, and intended use, and is listed as equivalent in FDA's approved drug products with therapeutic equivalence evaluations (orange book).

(e) "Therapeutic substitution" means the dispensing of a chemically different drug in the place of the drug originally prescribed by the patient's physician or other prescribing health care professional, including biologics and plasma-derived therapies. Therapeutic substitution does not include substitution of a generic equivalent.

§ 3302. Prescription drug denials. (a) A policy of accident and/or health insurance that covers prescription drugs shall not limit, reduce, or deny coverage for any drug if, prior to the limitation, reduction, or denial of coverage:

(1) Any insured was using the drug;

(2) Such insured or insureds were covered under the policy; and

(3) The drug was covered under the policy for such insured individual or individuals.

(b) A limitation, reduction, or denial of coverage includes removing a drug from the formulary or other drug list, imposing new prior authorization or other utilization management tools, or placing the drug on a formulary tier that increases the patient's cost-sharing obligations or otherwise increases the patient's cost-sharing obligations.

(c) Nothing in this section shall prohibit an insurer from making uniform changes in its benefit design that apply to all covered drugs, uniformly removing a drug from the formulary list for all insureds, or increasing cost-sharing obligations merely due to a percentage coinsurance payment that necessarily increases with an increase in the underlying drug prices.

(d) No therapeutic substitution of a medication by anyone authorized to dispense medications for self or home administration by a consumer shall be allowed without the express authorization of the original prescribing physician or health care professional and notice to the patient and the policy sponsor as provided for in section three thousand three hundred three of this article. Prior to making a therapeutic substitution in a patient's prescription including but not limited to changes in product selection and changes in dosage, the dispensing pharmacist shall:

(1) Verbally request the patient to agree to a change to the prescription, and explain that the change cannot be made unless both the patient and the prescribing physician (or other prescribing health care professional) expressly agree to the change;

(2) Verbally describe the proposed change that would be made to the prescription, including clearly identifying the originally prescribed medication and the medication that would be substituted for the originally prescribed medication; and

(3) Verbally inform the patient of the impact, if any, on the patient's out-of-pocket cost.

§ 3303. Switch communications/consumer right to know. (a) Any time a patient's prescribed medication is recommended to be switched to a medication other than that originally prescribed by the prescribing practitioner, 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)

provide a truthful, fair, and balanced explanation regarding the potential, ramifications of the therapeutic substitution, including but not limited to, that medications in the same therapeutic class are associated with different risks and benefits and may work differently in different patients.

§ 3304. Penalties. (a) Issuing or delivering or causing to be issued or delivered a switch communication that has not been approved and is not in compliance with the requirements of section three thousand three hundred three of this article is punishable by a fine not to exceed twenty-five thousand dollars.

(b) Providing a misrepresentation or false statement in a switch communication under section three thousand three hundred three of this article is punishable by a fine not to exceed twenty-five thousand dollars.

(c) Any other material violation of section three thousand three hundred three of this article is punishable by a fine not to exceed twenty-five thousand dollars.

§ 3305. 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) 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) 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) 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 the period deemed necessary by the prescribing physician or health care professional to determine the treatment's clinical effectiveness or a period of fourteen days.

(c) For medications with no generic equivalent and for which the prescribing physician in their clinical judgment feels 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 which is not otherwise covered by law.

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