

SENATE, No. 503

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:

Senator CHRIS A. BROWN

District 2 (Atlantic)

Senator JOSEPH P. CRYAN

District 20 (Union)

SYNOPSIS

Restricts certain practices by carriers and pharmacy benefits managers related to medications and drugs.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



1 **AN ACT** concerning health insurance coverage for medication and
2 supplementing Title 17B of the New Jersey Statutes.

3

4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6

7 1. As used in this act:

8 "Carrier" means an insurance company, health service
9 corporation, hospital service corporation, medical service
10 corporation, or health maintenance organization authorized to issue
11 health benefits plans in this State.

12 "Covered person" means a person on whose behalf a carrier
13 offering the plan is obligated to pay benefits or provide services
14 pursuant to the health benefits plan.

15 "Department" means the Department of Banking and Insurance.

16 "Generic equivalent" means a drug that is the same chemical
17 compound as another drug and is the same dosage form, strength,
18 route of administration, and intended use, and is listed as equivalent
19 in the U.S. Food and Drug Administration's Approved Drug
20 Products with Therapeutic Equivalence Evaluations, or "Orange
21 Book."

22 "Health benefits plan" means a benefits plan which pays or
23 provides hospital and medical expense benefits for covered
24 services, and is delivered or issued for delivery in this State by or
25 through a carrier. Health benefits plan includes, but is not limited
26 to, Medicare supplement coverage and risk contracts to the extent
27 not otherwise prohibited by federal law. For the purposes of this
28 act, health benefits plan shall not include the following plans,
29 policies, or contracts: accident only, credit, disability, long-term
30 care, TRICARE supplement coverage, coverage arising out of a
31 workers' compensation or similar law, automobile medical payment
32 insurance, personal injury protection insurance issued pursuant to
33 P.L.1972, c.70 (C.39:6A-1 et seq.), or hospital confinement
34 indemnity coverage.

35 "Pharmacy benefits manager" means a corporation, business, or
36 other entity, or unit within a corporation, business, or other entity,
37 that administers prescription drug benefits.

38 "Plan sponsor" means an employer or other entity that provides a
39 group health benefits plan.

40 "Prescriber" means a physician, advanced practice nurse, or
41 other prescriber licensed pursuant to Title 45 of the Revised
42 Statutes who is authorized to prescribe drugs pursuant to State law.

43 "Switch communication" means a written communication from a
44 carrier or a pharmacy benefits manager to a patient or the patient's
45 prescriber that recommends a patient's medication be switched by
46 the original prescriber to a different medication than the medication
47 originally prescribed by the prescriber.

1 "Therapeutic substitution" means the dispensing of a chemically
2 different drug in the place of the drug originally prescribed by the
3 prescriber, including biologics and plasma-derived therapies.
4 "Therapeutic substitution" shall not include substitution of a generic
5 equivalent.

6
7 2. a. A carrier that offers a health benefits plan that covers
8 prescription drugs shall not limit, reduce, or deny coverage for any
9 drug if, prior to the limitation, reduction, or denial of coverage:

10 (1) any covered person was using the drug;

11 (2) the covered person was covered under the plan; and

12 (3) the drug was covered under the plan for the covered person.

13 A limitation, reduction, or denial of coverage includes removing
14 a drug from the formulary or other drug list, imposing new prior
15 authorization or other utilization management tools, placing the
16 drug on a formulary tier that increases the covered person's cost-
17 sharing obligations, or otherwise increasing the covered person's
18 cost-sharing obligations.

19 b. Nothing in this section shall prohibit a carrier from making
20 uniform changes in its benefit design that apply to all covered
21 drugs, uniformly removing a drug from the formulary list for all
22 covered persons, or increasing cost-sharing obligations merely due
23 to a percentage coinsurance payment that necessarily increases with
24 an increase in the underlying drug prices.

25 c. A therapeutic substitution of a medication by any person
26 authorized to dispense medications for self or home administration
27 by a covered person shall not be allowed without the express
28 authorization of the original prescriber and a notice to the covered
29 person and the plan sponsor as provided for in section 3 of this act.

30 d. Prior to making a therapeutic substitution in a covered
31 person's prescription, including but not limited to, changes in
32 product selection and changes in dosage, a dispensing pharmacist
33 shall verbally:

34 (1) request the covered person to agree to a change to the
35 prescription, and explain that the change cannot be made unless
36 both the patient and the prescriber expressly agree to the change;

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

41 (3) inform the covered person of the impact, if any, on the
42 covered person's out-of-pocket cost.

43
44 3. a. If a carrier or a pharmacy benefits manager recommends
45 that a covered person's prescribed medication be switched to a
46 medication other than that originally prescribed by the prescriber,
47 the carrier or pharmacy benefits manager, as applicable, shall send a
48 switch communication to:

- 1 (1) the covered person, in which case the switch communication
- 2 shall provide information about why the switch is proposed and the
- 3 covered person's right to refuse the recommended change in
- 4 treatment; and
- 5 (2) the plan sponsor, in which case the switch communication
- 6 shall inform the plan sponsor of the pharmaceutical wholesale
- 7 acquisition cost, shown in currency form, of the recommended drug
- 8 and the wholesale acquisition cost, shown in currency form, of the
- 9 originally prescribed drug.
- 10 b. The carrier or pharmacy benefits manager, as applicable,
- 11 shall ensure that the switch communication:
- 12 (1) clearly identifies the originally prescribed medication and
- 13 the medication to which it has been proposed that the covered
- 14 person should be switched;
- 15 (2) provides information which is truthful, accurate, and not
- 16 misleading, with appropriate fair balance, consistent with the
- 17 United States Food and Drug Administration guidelines for
- 18 medications;
- 19 (3) includes current approved product labeling and information
- 20 about risks associated with the recommended medication;
- 21 (4) clearly acknowledges that no therapeutic substitution shall
- 22 be allowed without the express authorization of the original
- 23 prescriber;
- 24 (5) advises the covered person of his or her rights to:
- 25 (a) discuss the proposed change in treatment before the switch
- 26 takes place, including the right to a discussion with the covered
- 27 person's prescriber;
- 28 (b) file an appeal with the carrier as part of the Independent
- 29 Health Care Appeals Program established pursuant to sections 11
- 30 and 12 of P.L.1997, c.192 (C.26:2S-11 and 26:2S-12) to prevent the
- 31 switch if the switch is based on a financial incentive; and
- 32 (c) file a complaint with the department; and
- 33 (6) explain any cost-sharing changes for which the covered
- 34 person is responsible.
- 35 c. A copy of a switch communication sent to a covered person
- 36 by a carrier or a pharmacy benefits manager shall also be sent to the
- 37 prescriber.
- 38 d. Carriers and pharmacy benefits managers shall notify
- 39 covered persons and plan sponsors, of therapeutic substitutions and
- 40 any therapeutic substitution programs adopted by carriers or
- 41 pharmacy benefit managers in any health benefits plan.
- 42 e. The department shall create one form for carriers and
- 43 pharmacy benefit managers to use in providing switch
- 44 communications to covered persons, prescribers, carriers, and plan
- 45 sponsors.
- 46 f. Pursuant to section 5 of this act, the Commissioner of
- 47 Banking and Insurance, in consultation with the Commissioner of
- 48 Health, shall adopt rules and regulations governing switch

1 communications. The rules and regulations shall include, but not be
2 limited to, the following:

3 (1) procedures for verifying the accuracy of any switch
4 communication from a carrier and pharmacy benefits manager to
5 ensure that switch communications are truthful, accurate, and not
6 misleading based on cost to the covered person and carrier or plan
7 sponsor, the product package labeling, medical compendia
8 recognized by the Drug Utilization Review Board established
9 pursuant to section 2 of P.L.1998, c.41 (C.30:4D-17.17a), and peer-
10 reviewed medical literature, with appropriate references provided;

11 (2) except for a substitution due to the Food and Drug
12 Administration's withdrawal of a drug for prescription, a
13 requirement that all switch communications contain a prominent
14 notice on the first page that states: "This is not a product safety
15 notice. This is a promotional announcement from your health
16 insurance carrier or pharmacy benefits manager about one of your
17 current prescribed medications."; and

18 (3) a requirement that the notification of request for the change
19 shall:

20 (a) expressly state that the change involves a therapeutic
21 substitution, not a generic substitution;

22 (b) explain the difference between therapeutic substitution and
23 generic substitution; and

24 (c) provide a truthful, fair, and balanced explanation regarding
25 the potential ramifications of the therapeutic substitution, including
26 but not limited to, that medications in the same therapeutic class are
27 associated with different risks and benefits and may affect different
28 patients differently.

29

30 4. a. Notwithstanding any other law or contract to the contrary,
31 whenever a carrier that offers a health benefits plan restricts
32 coverage for a medication for the treatment of any medical
33 condition through the use of a step therapy or fail first protocol, the
34 carrier shall provide the prescriber access to a clear and convenient
35 process, at no charge to the prescriber or covered person, that the
36 prescriber may use to override the coverage restriction. The
37 prescriber may use the process, and the carrier shall provide
38 coverage for the medication prescribed by the prescriber, if:

39 (1) the prescriber, in the prescriber's professional judgment,
40 determines, at any time, that the drug preferred by the carrier as part
41 of a step therapy or fail first protocol has been ineffective in the
42 treatment of the covered person's disease or medical condition or
43 has caused an adverse reaction or other harm to the covered person;
44 or

45 (2) based on sound clinical evidence and medical and scientific
46 evidence, the prescriber, in the prescriber's professional judgment,
47 determines that:

1 (a) the drug preferred by the carrier or the pharmacy benefits
2 manager is expected to be ineffective based on the known relevant
3 physical or mental characteristics of the covered person and known
4 characteristics of the drug regimen, and is likely to adversely affect
5 patient compliance; or

6 (b) the preferred drug is expected to cause an adverse reaction
7 or other harm to the covered person.

8 b. The duration of any step therapy or fail first protocol shall
9 not be longer than the period deemed necessary by the prescriber to
10 determine the treatment's clinical effectiveness.

11 c. For medications with no generic equivalent and for which
12 the prescriber in their clinical judgment feels that no appropriate
13 therapeutic alternative is available, a carrier or pharmacy benefits
14 manager shall provide access to U.S. Food and Drug Administration
15 (FDA) labeled medications without restriction to treat the medical
16 conditions for which FDA labeled medication is available.

17
18 5. The Commissioner of Banking and Insurance, in
19 consultation with the Commissioner of Health, shall adopt, pursuant
20 to the "Administrative Procedure Act" P.L.1968, c.410 (C.52:14B-
21 1 et seq.), rules and regulations, including any penalty provisions
22 the commissioners deem necessary, to effectuate the purposes of
23 this act.

24
25 6. This act shall take effect on the 90th day next following
26 enactment.

27 28 29 STATEMENT

30
31 This bill places certain restrictions on health insurance carriers
32 and pharmacy benefits managers relating to the switching of drugs
33 and medication, and step therapy and fail first practices.

34 The bill requires that a health insurance carrier that offers a
35 health benefits plan that covers prescription drugs shall not limit,
36 reduce, or deny coverage for any drugs currently in use by a person
37 covered under the plan, except in certain situations. The bill also
38 places certain restrictions and disclosure requirements on
39 therapeutic substitutions of medications.

40 The bill also places certain requirements on carriers and pharmacy
41 benefits managers in situations in which a covered person's
42 prescribed medication is switched to a medication other than that
43 originally prescribed by the prescriber. The bill requires a switch
44 communication to be provided, which must contain certain
45 disclosures to covered persons and health benefit plan sponsors,
46 including the right of a covered person to file an appeal with respect
47 to the switch. The Department of Banking and Insurance is
48 required to create one form for carriers and pharmacy benefit

1 managers to use in providing switch communications to covered
2 persons, prescribers, carriers, and plan sponsors, and to adopt
3 certain rules and regulations governing switch communications, as
4 set forth in the bill.

5 The bill also provides that, notwithstanding any other law or
6 contract to the contrary, whenever a carrier that offers a health
7 benefits plan restricts coverage for a medication for the treatment of
8 any medical condition through the use of a step therapy or fail first
9 protocol, the carrier shall provide the prescriber access to a clear
10 and convenient process, at no charge to the prescriber or covered
11 person, that the prescriber may use to override the coverage
12 restriction. The prescriber may use the process, and the carrier shall
13 provide coverage for the medication prescribed by the prescriber, if:

14 (1) the prescriber, in the prescriber's professional judgment,
15 determines, at any time, that the drug preferred by the carrier as part
16 of a step therapy or fail first protocol has been ineffective in the
17 treatment of the covered person's disease or medical condition or
18 has caused an adverse reaction or other harm to the covered person;
19 or

20 (2) based on sound clinical evidence and medical and scientific
21 evidence, the prescriber, in the prescriber's professional judgment,
22 determines that:

- 23 • the drug preferred by the carrier or the pharmacy benefits
24 manager is expected to be ineffective based on the known
25 relevant physical or mental characteristics of the covered
26 person and known characteristics of the drug regimen, and is
27 likely to adversely affect patient compliance; or
- 28 • the preferred drug is expected to cause an adverse reaction
29 or other harm to the covered person.

30 The bill specifies that the duration of any step therapy or fail first
31 protocol shall not be longer than the period deemed necessary by
32 the prescriber to determine the treatment's clinical effectiveness.

33 For medications with no generic equivalent and for which the
34 prescriber in their clinical judgment feels that no appropriate
35 therapeutic alternative is available, a carrier or pharmacy benefits
36 manager shall provide access to U.S. Food and Drug Administration
37 (FDA) labeled medications without restriction to treat the medical
38 conditions for which FDA labeled medication is available.

39 Finally, the bill provides that the Commissioner of Banking and
40 Insurance, in consultation with the Commissioner of Health, shall
41 adopt, pursuant to the "Administrative Procedure Act" P.L.1968,
42 c.410 (C.52:14B-1 et seq.), rules and regulations, including any
43 penalty provisions the commissioners deem necessary, to effectuate
44 the purposes of the bill.