



99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

HB3549

by Rep. Laura Fine

SYNOPSIS AS INTRODUCED:

215 ILCS 134/45.1
215 ILCS 134/45.3 new
215 ILCS 134/45.4 new

Amends the Managed Care Reform and Patient Rights Act. Applies the medical exemptions process to all entities licensed in the State to sell a policy of group or individual accident and health insurance or health benefits plan. Provides certain exceptions upon which a step therapy override will always be provided. Sets clinical review criteria that must be used to establish step therapy protocols. Effective immediately.

LRB099 09324 MLM 29529 b

1 AN ACT concerning regulation.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 5. The Managed Care Reform and Patient Rights Act
5 is amended by changing Section 45.1 and by adding Sections 45.3
6 and 45.4 as follows:

7 (215 ILCS 134/45.1)

8 Sec. 45.1. Medical exceptions procedures required.

9 (a) Notwithstanding any other provision of law, on or after
10 the effective date of this amendatory Act of the 99th General
11 Assembly, every insurer licensed in this State to sell a policy
12 of group or individual accident and health insurance or a
13 health benefits plan shall ~~Every health carrier that offers a~~
14 ~~qualified health plan, as defined in the federal Patient~~
15 ~~Protection and Affordable Care Act of 2010 (Public Law~~
16 ~~111 148), as amended by the federal Health Care and Education~~
17 ~~Reconciliation Act of 2010 (Public Law 111 152), and any~~
18 ~~amendments thereto, or regulations or guidance issued under~~
19 ~~those Acts (collectively, "the Federal Act"), directly to~~
20 ~~consumers in this State shall~~ establish and maintain a medical
21 exceptions process that allows covered persons or their
22 authorized representatives to request any clinically
23 appropriate prescription drug when (1) the drug is not covered

1 based on the health benefit plan's formulary; (2) the health
2 benefit plan is discontinuing coverage of the drug on the
3 plan's formulary for reasons other than safety or other than
4 because the prescription drug has been withdrawn from the
5 market by the drug's manufacturer; (3) the prescription drug
6 alternatives required to be used in accordance with a step
7 therapy requirement (A) has been ineffective in the treatment
8 of the enrollee's disease or medical condition or, based on
9 both sound clinical evidence and medical and scientific
10 evidence, the known relevant physical or mental
11 characteristics of the enrollee, and the known characteristics
12 of the drug regimen, is likely to be ineffective or adversely
13 affect the drug's effectiveness or patient compliance or (B)
14 has caused or, based on sound medical evidence, is likely to
15 cause an adverse reaction or harm to the enrollee; or (4) the
16 number of doses available under a dose restriction for the
17 prescription drug (A) has been ineffective in the treatment of
18 the enrollee's disease or medical condition or (B) based on
19 both sound clinical evidence and medical and scientific
20 evidence, the known relevant physical and mental
21 characteristics of the enrollee, and known characteristics of
22 the drug regimen, is likely to be ineffective or adversely
23 affect the drug's effective or patient compliance.

24 (b) The health carrier's established medical exceptions
25 procedures must require, at a minimum, the following:

26 (1) Any request for approval of coverage made verbally

1 or in writing (regardless of whether made using a paper or
2 electronic form or some other writing) at any time shall be
3 reviewed by appropriate health care professionals.

4 (2) The health carrier must, within 72 hours after
5 receipt of a request made under subsection (a) of this
6 Section, either approve or deny the request. In the case of
7 a denial, the health carrier shall provide the covered
8 person or the covered person's authorized representative
9 and the covered person's prescribing provider with the
10 reason for the denial, an alternative covered medication,
11 if applicable, and information regarding the procedure for
12 submitting an appeal to the denial.

13 (3) In the case of an expedited coverage determination,
14 the health carrier must either approve or deny the request
15 within 24 hours after receipt of the request. In the case
16 of a denial, the health carrier shall provide the covered
17 person or the covered person's authorized representative
18 and the covered person's prescribing provider with the
19 reason for the denial, an alternative covered medication,
20 if applicable, and information regarding the procedure for
21 submitting an appeal to the denial.

22 (c) A step therapy override determination request shall be
23 expeditiously granted if:

24 (1) the required prescription drug is contraindicated
25 or will likely cause an adverse reaction by or physical or
26 mental harm to the patient;

1 (2) the required prescription drug is expected to be
2 ineffective based on the known relevant physical or mental
3 characteristics of the patient and the known
4 characteristics of the prescription drug regimen;

5 (3) the patient has tried the required prescription
6 drug while under their current or a previous health
7 insurance or health benefit plan, or another prescription
8 drug in the same pharmacologic class or with the same
9 mechanism of action and such prescription drug was
10 discontinued due to lack of efficacy or effectiveness,
11 diminished effect, or an adverse event;

12 (4) the required prescription drug is not in the best
13 interest of the patient, based on medical appropriateness;
14 or

15 (5) the patient is stable on a prescription drug
16 selected by their health care provider for the medical
17 condition under consideration.

18 (d) Upon the granting of an exception request, the insurer,
19 health plan, utilization review organization, or other entity
20 shall authorize the dispensing of and coverage for the drug
21 prescribed by the enrollee's treating health care provider,
22 provided the drug is a covered drug under the policy or
23 contract.

24 ~~(e) Notwithstanding any other provision of this Section,~~
25 ~~nothing in this Section shall be interpreted or implemented in~~
26 ~~a manner not consistent with the Federal Act.~~

1 (Source: P.A. 98-1035, eff. 8-25-14.)

2 (215 ILCS 134/45.3 new)

3 Sec. 45.3. Clinical review criteria used in step therapy
4 protocols. Notwithstanding any other provision of law, on or
5 after the effective date of this amendatory Act of the 99th
6 General Assembly, every insurer licensed in this State to sell
7 a policy of group or individual accident and health insurance
8 or a health benefits plan shall base their clinical review
9 criteria for step therapy protocols on clinical practice
10 guidelines that:

11 (1) recommend that the prescription drugs be taken in
12 the specific sequence required by the step therapy
13 protocol;

14 (2) are developed and endorsed by an independent,
15 multidisciplinary panel of experts not affiliated with an
16 insurer, health plan or utilization review organization;

17 (3) are based on high quality studies, research, and
18 medical practice;

19 (4) are created by an explicit and transparent process
20 that:

21 (A) minimizes biases and conflicts of interest;

22 (B) explains the relationship between treatment
23 options and outcomes;

24 (C) rates the quality of the evidence supporting
25 recommendations; and

1 (D) considers relevant patient subgroups and
2 preferences; and
3 (5) are continually updated through a review of new
4 evidence and research.

5 The Department shall adopt any rules necessary to enforce
6 this Section.

7 (215 ILCS 134/45.4 new)

8 Sec. 45.4. Cost sharing.

9 (a) Notwithstanding any other provision of law, on or after
10 the effective date of this amendatory Act of the 99th General
11 Assembly, every insurer licensed in this State to sell a policy
12 of group or individual accident and health insurance or a
13 health benefits plan shall ensure that where step therapy
14 protocols are used to impose clinical prerequisites for
15 coverage of prescription drugs, such drugs shall be available
16 to the consumer at the preferred cost-sharing level for the
17 item once the clinical prerequisites have been satisfied.

18 (b) This Section shall not be construed to prevent insurers
19 from using tiered copayment structures.

20 Section 99. Effective date. This Act takes effect upon
21 becoming law.