
SENATE BILL 6233

State of Washington

65th Legislature

2018 Regular Session

By Senators Cleveland, Rivers, Kuderer, Fain, and Conway

Read first time 01/10/18. Referred to Committee on Health & Long Term Care.

1 AN ACT Relating to regulating the use of step therapy protocols
2 by providing a simple and expeditious process for exceptions to the
3 protocols that the health care provider deems not in the best
4 interests of the patient; adding new sections to chapter 48.43 RCW;
5 and creating a new section.

6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

7 NEW SECTION. **Sec. 1.** (1) The legislature finds the following:

8 (a) Health insurance plans are increasingly making use of step
9 therapy protocols under which patients are required to try one or
10 more prescription drugs before coverage is provided for a drug
11 selected by the patient's health care provider;

12 (b) Such step therapy protocols, where they are based on well-
13 developed scientific standards and administered in a flexible manner
14 that takes into account the individual needs of patients, can play an
15 important role in controlling health care costs;

16 (c) In some cases, requiring a patient to follow a step therapy
17 protocol may have adverse and even dangerous consequences for the
18 patient who may either not realize a benefit from taking a
19 prescription drug or may suffer harm from taking an inappropriate
20 drug;

1 (d) Without uniform policies in the state for step therapy
2 protocols, all patients may not receive the equivalent or most
3 appropriate treatment; and

4 (e) It is imperative that step therapy protocols in the state
5 preserve the health care provider's right to make treatment decisions
6 in the best interest of the patient.

7 (2) Therefore, the legislature declares it a matter of public
8 interest that it require health insurers to base step therapy
9 protocols on appropriate clinical practice guidelines or published
10 peer reviewed data developed by independent experts with knowledge of
11 the condition or conditions under consideration; that patients be
12 exempt from step therapy protocols when those protocols are
13 inappropriate or otherwise not in the best interest of the patients;
14 and that patients have access to a fair, transparent, and independent
15 process for requesting an exception to a step therapy protocol when
16 the patient's physician deems appropriate.

17 NEW SECTION. **Sec. 2.** A new section is added to chapter 48.43
18 RCW to read as follows:

19 The definitions in this section apply throughout this section and
20 sections 3 and 4 of this act unless the context clearly requires
21 otherwise.

22 (1) "Clinical practice guidelines" means a systemically developed
23 statement to assist decision making by health care providers and
24 patient decisions about appropriate health care for specific clinical
25 circumstances and conditions.

26 (2) "Clinical review criteria" means the written screening
27 procedures, decision abstracts, clinical protocols, and practice
28 guidelines used by an insurer, health plan, or utilization review
29 organization to determine the medical necessity and appropriateness
30 of health care services.

31 (3) "Medically necessary" means health services and supplies that
32 under the applicable standard of care are appropriate: (a) To improve
33 or preserve health, life, or function; (b) to slow the deterioration
34 of health, life, or function; or (c) for the early screening,
35 prevention, evaluation, diagnosis, or treatment of a disease,
36 condition, illness, or injury.

37 (4) "Step therapy exception" means that a step therapy protocol
38 should be overridden in favor of immediate coverage of the health
39 care provider's selected prescription drug.

1 (5) "Step therapy protocol" means a protocol or program that
2 establishes the specific sequence in which prescription drugs for a
3 specified medical condition and medically appropriate for a
4 particular patient are covered by an insurer or health plan.

5 (6) "Utilization review organization" means an entity that
6 conducts utilization review, other than an insurer or health plan
7 performing utilization review for its own health benefit plans.

8 NEW SECTION. **Sec. 3.** A new section is added to chapter 48.43
9 RCW to read as follows:

10 (1) Clinical review criteria used to establish a step therapy
11 protocol shall be based on clinical practice guidelines that:

12 (a) Recommend that the prescription drugs be taken in the
13 specific sequence required by the step therapy protocol;

14 (b) Are developed and endorsed by a multidisciplinary panel of
15 experts that manages conflicts of interest among the members of the
16 writing and review groups by:

17 (i) Requiring members to disclose any potential conflict of
18 interest with entities, including insurers, health plans, and
19 pharmaceutical manufacturers and recuse themselves of voting if they
20 have a conflict of interest;

21 (ii) Using a methodologist to work with writing groups to provide
22 objectivity in data analysis and ranking of evidence through the
23 preparation of evidence tables and facilitating consensus; and

24 (iii) Offering opportunities for public review and comments;

25 (c) Are based on high quality studies, research, and medical
26 practice;

27 (d) Are created by an explicit and transparent process that:

28 (i) Minimizes biases and conflicts of interest;

29 (ii) Explains the relationship between treatment options and
30 outcomes;

31 (iii) Rates the quality of the evidence supporting
32 recommendations; and

33 (iv) Considers relevant patient subgroups and preferences;

34 (e) Are continually updated through a review of new evidence,
35 research, and newly developed treatments.

36 (2) In the absence of clinical guidelines that meet the
37 requirements in subsection (1)(b) of this section, peer-reviewed
38 publications may be substituted.

1 (3) When establishing a step therapy protocol, a utilization
2 review organization shall also take into account the needs of
3 atypical patient populations and diagnoses when establishing clinical
4 review criteria.

5 (4) This section does not require insurers, health plans, or the
6 state to set up a new entity to develop clinical review criteria used
7 for step therapy protocols.

8 NEW SECTION. **Sec. 4.** A new section is added to chapter 48.43
9 RCW to read as follows:

10 (1) When coverage of a prescription drug for the treatment of any
11 medical condition is restricted for use by an insurer, health plan,
12 or utilization review organization through the use of a step therapy
13 protocol, the patient and prescribing practitioner must have access
14 to a clear, readily accessible, and convenient process to request a
15 step therapy exception. An insurer, health plan, or utilization
16 review organization may use its existing medical exceptions process
17 to satisfy this requirement. The process must be easily accessible on
18 the insurer's, health plan's, or utilization review organization's
19 web site.

20 (2) A step therapy exception must be expeditiously granted if:

21 (a) The required prescription drug is contraindicated or will
22 likely cause an adverse reaction by or physical or mental harm to the
23 patient;

24 (b) The required prescription drug is expected to be ineffective
25 based on the known clinical characteristics of the patient and the
26 known characteristics of the prescription drug regimen;

27 (c) The patient has tried the required prescription drug while
28 under their current or a previous health insurance or health benefit
29 plan, or another prescription drug in the same pharmacologic class or
30 with the same mechanism of action and such prescription drug was
31 discontinued due to lack of efficacy or effectiveness, diminished
32 effect, or an adverse event;

33 (d) The required prescription drug is not in the best interest of
34 the patient, based on medical necessity; and

35 (e) The patient is stable on a prescription drug selected by
36 their health care provider for the medical condition under
37 consideration while on a current or previous health insurance or
38 health benefit plan.

1 (3) Upon the granting of a step therapy exception, the insurer,
2 health plan, or utilization review organization shall authorize
3 coverage for the prescription drug prescribed by the patient's
4 treating health care provider.

5 (4) The insurer, health plan, or utilization review organization
6 shall respond to a step therapy exception request or an appeal within
7 seventy-two hours of receipt. In cases where exigent circumstances
8 exist, an insurer, health plan, or utilization review organization
9 shall respond within twenty-four hours of receipt. Should a response
10 by an insurer, health plan, or utilization review organization not be
11 received within the time allotted, the exception or appeal is deemed
12 granted.

13 (5) Any step therapy exception as defined in section 2 of this
14 act is eligible for appeal by an insured.

15 (6) This section does not prevent:

16 (a) An insurer, health plan, or utilization review organization
17 from requiring a patient to try an AB-rated generic equivalent prior
18 to providing coverage for the equivalent branded prescription drug;
19 and

20 (b) A health care provider from prescribing a prescription drug
21 that is determined to be medically appropriate.

22 NEW SECTION. **Sec. 5.** A new section is added to chapter 48.43
23 RCW to read as follows:

24 The commissioner shall adopt rules necessary for the
25 implementation of sections 2 through 4 and 6 of this act.

26 NEW SECTION. **Sec. 6.** A new section is added to chapter 48.43
27 RCW to read as follows:

28 Sections 2 through 5 of this act apply only to health insurance
29 and health benefit plans delivered, issued for delivery, or renewed
30 on or after January 1, 2019.

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