
SENATE BILL 5806

State of Washington

66th Legislature

2019 Regular Session

By Senators Cleveland and Rivers

1 AN ACT Relating to regulating and reporting of utilization
2 management in prescription drug benefits; adding new sections to
3 chapter 48.43 RCW; and creating a new section.

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

5 NEW SECTION. **Sec. 1.** A new section is added to chapter 48.43
6 RCW to read as follows:

7 The definitions in this section apply throughout this section and
8 sections 2 and 3 of this act unless the context clearly requires
9 otherwise.

10 (1) "Clinical practice guidelines" means a systemically developed
11 statement to assist decision making by health care providers and
12 patients about appropriate health care for specific clinical
13 circumstances and conditions.

14 (2) "Clinical review criteria" means the written screening
15 procedures, decision abstracts, clinical protocols, and practice
16 guidelines used by a health carrier, health plan, or utilization
17 review organization to determine the medical necessity and
18 appropriateness of health care services.

19 (3) "Emergency fill" means a limited dispensed amount of
20 medication that allows time for the processing of a prior
21 authorization request.

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

7 (5) "Prescription drug utilization management" means a set of
8 formal techniques used by a health carrier or delegate of the health
9 carrier, such as a pharmacy benefit manager or third-party
10 administrator, that are designed to monitor the use of or evaluate
11 the medical necessity, appropriateness, efficacy, or efficiency of
12 prescription drugs including, but not limited to, prior authorization
13 and step therapy protocol.

14 (6) "Prior authorization" means a mandatory process that a
15 carrier or its designated or contracted representative requires a
16 provider or facility to follow to determine if a service is a benefit
17 and meets the requirements for medical necessity, clinical
18 appropriateness, level of care, or effectiveness in relation to the
19 applicable plan. Prior authorization occurs before the service is
20 delivered.

21 (7) "Step therapy exception" means that a step therapy protocol
22 should be overridden in favor of immediate coverage of the health
23 care provider's selected prescription drug.

24 (8) "Step therapy protocol" means a protocol or program that
25 establishes the specific sequence in which prescription drugs for a
26 specified medical condition and medically appropriate for a
27 particular patient are covered by a health carrier or health plan.

28 (9) "Utilization review organization" means an entity that
29 conducts utilization review, other than a health carrier or health
30 plan performing utilization review for its own health benefit plans.

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

33 (1) Clinical review criteria used to establish a prescription
34 drug utilization management protocol must be based on clinical
35 practice guidelines that:

36 (a) Are developed and endorsed by a multidisciplinary panel of
37 experts that manages conflicts of interest among the members of the
38 writing and review groups by:

1 (i) Requiring members to disclose any potential conflicts of
2 interest with entities, including health carriers, health plans, and
3 pharmaceutical manufacturers, and to recuse themselves of voting if
4 they have a conflict of interest;

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

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

9 (b) Are based on high quality studies, research, and medical
10 practice;

11 (c) Are created by an explicit and transparent process that:

12 (i) Minimizes biases and conflicts of interest;

13 (ii) Explains the relationship between treatment options and
14 outcomes;

15 (iii) Rates the quality of the evidence supporting
16 recommendations; and

17 (iv) Considers relevant patient subgroups and preferences; and

18 (d) Are continually updated through a review of new evidence,
19 research, and newly developed treatments.

20 (2) In the absence of clinical guidelines that meet the
21 requirements in subsection (1)(a) of this section, peer-reviewed
22 publications may be substituted.

23 (3) When establishing a prescription drug utilization management
24 protocol, a utilization review organization shall also take into
25 account the needs of atypical patient populations and diagnoses when
26 establishing clinical review criteria.

27 (4) This section does not require health carriers, health plans,
28 or the state to set up a new entity to develop clinical review
29 criteria used for prescription drug utilization management.

30 (5) This section applies only to health insurance and health
31 benefit plans delivered, issued for delivery, or renewed on or after
32 January 1, 2021.

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

35 (1) When coverage of a prescription drug for the treatment of any
36 medical condition is restricted for use by a health carrier, health
37 plan, or utilization review organization through the use of a
38 prescription drug utilization management protocol, the patient and
39 prescribing practitioner must have access to a clear, readily

1 accessible, and convenient process to request an exception. A health
2 carrier, health plan, or utilization review organization may use its
3 existing medical exceptions process to satisfy this requirement. The
4 process must be easily accessible on the health carrier, health plan,
5 or utilization review organization's web site. Approval criteria must
6 be clearly posted on its web site, providing specific information on
7 documentation and other criteria. This information must be in plain
8 language and understandable to providers and patients.

9 (2) Health carriers must disclose all rules related to the
10 prescription drug utilization management process to all participating
11 providers, including the specific, related information and
12 documentation that must be submitted in order to be considered a
13 completed request.

14 (3) An exception must be expeditiously granted if:

15 (a) The required prescription drug is contraindicated or will
16 likely cause an adverse reaction by, or physical or mental harm to,
17 the patient;

18 (b) The required prescription drug is expected to be ineffective
19 based on the known clinical characteristics of the patient and the
20 known characteristics of the prescription drug regimen;

21 (c) The patient has tried the required prescription drug while
22 under his or her current or a previous health insurance or health
23 benefit plan, or another prescription drug in the same pharmacologic
24 class or with the same mechanism of action and such prescription drug
25 was discontinued due to lack of efficacy or effectiveness, diminished
26 effect, or an adverse event;

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

29 (e) The patient is stable on a prescription drug selected by
30 their health care provider for the medical condition under
31 consideration while on a current or previous health insurance or
32 health benefit plan.

33 (4) Upon the granting of an exception, the health carrier, health
34 plan, or utilization review organization shall authorize coverage for
35 the prescription drug prescribed by the patient's treating health
36 care provider.

37 (5) The health carrier, health plan, or utilization review
38 organization shall respond to an exception request or an appeal
39 within seventy-two hours of receipt. In cases where exigent
40 circumstances exist, a health carrier, health plan, or utilization

1 review organization shall respond within twenty-four hours of
2 receipt. If a response by a health carrier, health plan, or
3 utilization review organization is not received within the time
4 allotted, the exception or appeal is deemed granted.

5 (6) Health carriers must cover an emergency supply fill if the
6 health care provider determines an emergency fill is necessary to
7 keep the patient stable while the exception is being processed.

8 (7) When responding to a prescription drug utilization management
9 request, a health carrier, health plan, or utilization review
10 organization shall clearly state in their response if the service was
11 approved or denied. The health carrier must provide a specific reason
12 for the denial and use evidence-based peer reviewed literature for
13 the basis of the denial. If the denial is based on specific payer
14 policy, clinical criteria, or peer-reviewed literature, the denial
15 must include policy language and an external appeals process. If the
16 request from the participating provider or facility is denied for
17 administrative reasons, or for not including all the necessary
18 information, the health carrier, health plan, or utilization review
19 organization must inform the provider or facility what additional
20 information is needed and the deadline for its submission.

21 (8) The health carrier, health plan, or utilization review
22 organization must permit a stabilized patient to remain on a drug
23 while the prescription drug utilization management is addressed,
24 including the appeals process.

25 (9) A health carrier must provide ninety days' notice for any new
26 rules that apply to prescription drug utilization management
27 protocols. New health carrier rules or policies may not be applied
28 retroactively.

29 (10) Any exception as defined in section 1 of this act is
30 eligible for appeal by an insured.

31 (11) This section does not prevent:

32 (a) A health carrier, health plan, or utilization review
33 organization from requiring a patient to try an AB-rated generic
34 equivalent prior to providing coverage for the equivalent branded
35 prescription drug; and

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

38 (12) This section applies only to health insurance and health
39 benefit plans delivered, issued for delivery, or renewed on or after
40 January 1, 2021.

1 NEW SECTION. **Sec. 4.** The commissioner shall adopt rules
2 necessary for the implementation of this act.

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