

CERTIFICATION OF ENROLLMENT

ENGROSSED SUBSTITUTE HOUSE BILL 1879

Chapter 171, Laws of 2019

66th Legislature
2019 Regular Session

PRESCRIPTION DRUG UTILIZATION MANAGEMENT

EFFECTIVE DATE: July 28, 2019

Passed by the House April 18, 2019
Yeas 94 Nays 0

FRANK CHOPP

Speaker of the House of Representatives

Passed by the Senate April 12, 2019
Yeas 46 Nays 0

CYRUS HABIB

President of the Senate

Approved April 29, 2019 2:20 PM

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **ENGROSSED SUBSTITUTE HOUSE BILL 1879** as passed by the House of Representatives and the Senate on the dates hereon set forth.

BERNARD DEAN

Chief Clerk

FILED

April 30, 2019

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE HOUSE BILL 1879

AS AMENDED BY THE SENATE

Passed Legislature - 2019 Regular Session

State of Washington 66th Legislature 2019 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Jenkins, Cody, Harris, Macri, DeBolt, Pollet, Robinson, Tharinger, and Doglio)

READ FIRST TIME 02/22/19.

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 rules, medical protocols, and clinical practice
16 guidelines used by a health carrier or prescription drug utilization
17 management entity as an element in the evaluation of medical
18 necessity and appropriateness of requested prescription drugs under a
19 health plan.

1 (3) "Emergency fill" means a limited dispensed amount of
2 medication that allows time for the processing of prescription drug
3 utilization management.

4 (4) "Medically appropriate" means prescription drugs that under
5 the applicable standard of care are appropriate: (a) To improve or
6 preserve health, life, or function; (b) to slow the deterioration of
7 health, life, or function; or (c) for the early screening,
8 prevention, evaluation, diagnosis, or treatment of a disease,
9 condition, illness, or injury.

10 (5) "Prescription drug utilization management" means a set of
11 formal techniques used by a health carrier or prescription drug
12 utilization management entity, that are designed to monitor the use
13 of or evaluate the medical necessity, appropriateness, efficacy, or
14 efficiency of prescription drugs including, but not limited to, prior
15 authorization and step therapy protocols.

16 (6) "Prescription drug utilization management entity" means an
17 entity affiliated with, under contract with, or acting on behalf of a
18 health carrier to perform prescription drug utilization management.

19 (7) "Prior authorization" means a mandatory process that a
20 carrier or prescription drug utilization management entity requires a
21 provider or facility to follow to determine if a service is a benefit
22 and meets the requirements for medical necessity, clinical
23 appropriateness, level of care, or effectiveness in relation to the
24 applicable plan.

25 (8) "Step therapy protocol" means a protocol or program that
26 establishes the specific sequence in which prescription drugs for a
27 specified medical condition will be covered by a health carrier.

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

30 For health plans delivered, issued for delivery, or renewed on or
31 after January 1, 2021, clinical review criteria used to establish a
32 prescription drug utilization management protocol must be evidence-
33 based and updated on a regular basis through review of new evidence,
34 research, and newly developed treatments.

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

37 For health plans delivered, issued for delivery, or renewed on or
38 after January 1, 2021:

1 (1) When coverage of a prescription drug for the treatment of any
2 medical condition is subject to prescription drug utilization
3 management, the patient and prescribing practitioner must have access
4 to a clear, readily accessible, and convenient process to request an
5 exception through which the prescription drug utilization management
6 can be overridden in favor of coverage of a prescription drug
7 prescribed by a treating health care provider. A health carrier or
8 prescription drug utilization management entity may use its existing
9 medical exceptions process to satisfy this requirement. The process
10 must be easily accessible on the health carrier and prescription drug
11 utilization management entity's web site. Approval criteria must be
12 clearly posted on the health carrier and prescription drug
13 utilization management entity's web site. This information must be in
14 plain language and understandable to providers and patients.

15 (2) Health carriers must disclose all rules and criteria related
16 to the prescription drug utilization management process to all
17 participating providers, including the specific information and
18 documentation that must be submitted by a health care provider or
19 patient to be considered a complete exception request.

20 (3) An exception request must be granted if the health carrier or
21 prescription drug utilization management entity determines that the
22 evidence submitted by the provider or patient is sufficient to
23 establish that:

24 (a) The required prescription drug is contraindicated or will
25 likely cause a clinically predictable adverse reaction by the
26 patient;

27 (b) The required prescription drug is expected to be ineffective
28 based on the known clinical characteristics of the patient and the
29 known characteristics of the prescription drug regimen;

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

36 (d) The patient is currently experiencing a positive therapeutic
37 outcome on a prescription drug recommended by the patient's provider
38 for the medical condition under consideration while on his or her
39 current or immediately preceding health plan, and changing to the

1 required prescription drug may cause clinically predictable adverse
2 reactions, or physical or mental harm to, the patient; or

3 (e) The required prescription drug is not in the best interest of
4 the patient, based on documentation of medical appropriateness,
5 because the patient's use of the prescription drug is expected to:

6 (i) Create a barrier to the patient's adherence to or compliance
7 with the patient's plan of care;

8 (ii) Negatively impact a comorbid condition of the patient;

9 (iii) Cause a clinically predictable negative drug
10 interaction; or

11 (iv) Decrease the patient's ability to achieve or maintain
12 reasonable functional ability in performing daily activities.

13 (4) Upon the granting of an exception, the health carrier or
14 prescription drug utilization management entity shall authorize
15 coverage for the prescription drug prescribed by the patient's
16 treating health care provider.

17 (5) (a) For nonurgent exception requests, the health carrier or
18 prescription drug utilization management entity must:

19 (i) Within three business days notify the treating health care
20 provider that additional information, as disclosed under subsection
21 (2) of this section, is required in order to approve or deny the
22 exception request, if the information provided is not sufficient to
23 approve or deny the request; and

24 (ii) Within three business days of receipt of sufficient
25 information from the treating health care provider as disclosed under
26 subsection (2) of this section, approve a request if the information
27 provided meets at least one of the conditions referenced in
28 subsection (3) of this section or if deemed medically appropriate, or
29 deny a request if the requested service does not meet at least one of
30 the conditions referenced in subsection (3) of this section.

31 (b) For urgent exception requests, the health carrier or
32 prescription drug utilization management entity must:

33 (i) Within one business day notify the treating health care
34 provider that additional information, as disclosed under subsection
35 (2) of this section, is required in order to approve or deny the
36 exception request, if the information provided is not sufficient to
37 approve or deny the request; and

38 (ii) Within one business day of receipt of sufficient information
39 from the treating health care provider as disclosed under subsection
40 (2) of this section, approve a request if the information provided

1 meets at least one of the conditions referenced in subsection (3) of
2 this section or if deemed medically appropriate, or deny a request if
3 the requested service does not meet at least one of the conditions
4 referenced in subsection (3) of this section.

5 (c) If a response by a health carrier or prescription drug
6 utilization management entity is not received within the time frames
7 established under this section, the exception request is deemed
8 granted.

9 (d) For purposes of this subsection, exception requests are
10 considered urgent when an enrollee is experiencing a health condition
11 that may seriously jeopardize the enrollee's life, health, or ability
12 to regain maximum function, or when an enrollee is undergoing a
13 current course of treatment using a nonformulary drug.

14 (6) Health carriers must cover an emergency supply fill if a
15 treating health care provider determines an emergency fill is
16 necessary to keep the patient stable while the exception request is
17 being processed. This exception shall not be used to solely justify
18 any further exemption.

19 (7) When responding to a prescription drug utilization management
20 exception request, a health carrier or prescription drug utilization
21 management entity shall clearly state in their response if the
22 exception request was approved or denied. The health carrier must use
23 clinical review criteria as referenced in section 2 of this act for
24 the basis of any denial. Any denial must be based upon and include
25 the specific clinical review criteria relied upon for the denial and
26 include information regarding how to appeal denial of the exception
27 request. If the exception request from a treating health care
28 provider is denied for administrative reasons, or for not including
29 all the necessary information, the health carrier or prescription
30 drug utilization management entity must inform the provider what
31 additional information is needed and the deadline for its submission.

32 (8) The health carrier or prescription drug utilization
33 management entity must permit a stabilized patient to remain on a
34 drug during an exception request process.

35 (9) A health carrier must provide sixty days' notice to providers
36 and patients for any new policies or procedures applicable to
37 prescription drug utilization management protocols. New health
38 carrier policies or procedures may not be applied retroactively.

39 (10) This section does not prevent:

1 (a) A health carrier or prescription drug utilization management
2 entity from requiring a patient to try an AB-rated generic equivalent
3 or a biological product that is an interchangeable biological product
4 prior to providing coverage for the equivalent branded prescription
5 drug;

6 (b) A health carrier or prescription drug utilization management
7 entity from denying an exception for a drug that has been removed
8 from the market due to safety concerns from the federal food and drug
9 administration; or

10 (c) A health care provider from prescribing a prescription drug
11 that is determined to be medically appropriate.

12 NEW SECTION. **Sec. 4.** The insurance commissioner shall adopt
13 rules necessary for the implementation of this act.

Passed by the House April 18, 2019.

Passed by the Senate April 12, 2019.

Approved by the Governor April 29, 2019.

Filed in Office of Secretary of State April 30, 2019.

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