
HOUSE BILL 1356

State of Washington

68th Legislature

2023 Regular Session

By Representative Reeves

1 AN ACT Relating to reducing prescription drug costs by
2 eliminating barriers impeding access to biosimilar medicines;
3 amending RCW 48.43.420 and 41.05.410; and creating a new section.

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

5 NEW SECTION. **Sec. 1.** The legislature finds that increasing
6 access to biosimilar medicines has the potential to significantly
7 reduce prescription drug costs. Biosimilar medicines are approved
8 according to the same food and drug administration standards of
9 pharmaceutical quality, safety, and efficacy as their reference
10 medicines. Therefore, it is the intent of the legislature to
11 eliminate barriers impeding access to biosimilar medicines and the
12 savings they can provide.

13 **Sec. 2.** RCW 48.43.420 and 2019 c 171 s 3 are each amended to
14 read as follows:

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

17 (1) When coverage of a prescription drug for the treatment of any
18 medical condition is subject to prescription drug utilization
19 management, the patient and prescribing practitioner must have access
20 to a clear, readily accessible, and convenient process to request an

1 exception through which the prescription drug utilization management
2 can be overridden in favor of coverage of a prescription drug
3 prescribed by a treating health care provider. A health carrier or
4 prescription drug utilization management entity may use its existing
5 medical exceptions process to satisfy this requirement. The process
6 must be easily accessible on the health carrier and prescription drug
7 utilization management entity's website. Approval criteria must be
8 clearly posted on the health carrier and prescription drug
9 utilization management entity's website. This information must be in
10 plain language and understandable to providers and patients.

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

16 (3) An exception request must be granted if the health carrier or
17 prescription drug utilization management entity determines that the
18 evidence submitted by the provider or patient is sufficient to
19 establish that:

20 (a) The required prescription drug is contraindicated or will
21 likely cause a clinically predictable adverse reaction by the
22 patient;

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

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

32 (d) The patient is currently experiencing a positive therapeutic
33 outcome on a prescription drug recommended by the patient's provider
34 for the medical condition under consideration while on his or her
35 current or immediately preceding health plan, and changing to the
36 required prescription drug may cause clinically predictable adverse
37 reactions, or physical or mental harm to, the patient; or

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

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

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

4 (iii) Cause a clinically predictable negative drug
5 interaction; or

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

8 (4) Upon the granting of an exception, the health carrier or
9 prescription drug utilization management entity shall authorize
10 coverage for the prescription drug prescribed by the patient's
11 treating health care provider.

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

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

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

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

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

33 (ii) Within one business day of receipt of sufficient information
34 from the treating health care provider as disclosed under subsection
35 (2) of this section, approve a request if the information provided
36 meets at least one of the conditions referenced in subsection (3) of
37 this section or if deemed medically appropriate, or deny a request if
38 the requested service does not meet at least one of the conditions
39 referenced in subsection (3) of this section.

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

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

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

15 (7) When responding to a prescription drug utilization management
16 exception request, a health carrier or prescription drug utilization
17 management entity shall clearly state in their response if the
18 exception request was approved or denied. The health carrier must use
19 clinical review criteria as referenced in RCW 48.43.410 for the basis
20 of any denial. Any denial must be based upon and include the specific
21 clinical review criteria relied upon for the denial and include
22 information regarding how to appeal denial of the exception request.
23 If the exception request from a treating health care provider is
24 denied for administrative reasons, or for not including all the
25 necessary information, the health carrier or prescription drug
26 utilization management entity must inform the provider what
27 additional information is needed and the deadline for its submission.

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

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

35 (10) This section does not prevent:

36 (a) A health carrier or prescription drug utilization management
37 entity from requiring a patient to try an AB-rated generic equivalent
38 or a biological product that is an interchangeable biological or
39 biosimilar product prior to providing coverage for the equivalent
40 branded prescription drug;

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

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

7 **Sec. 3.** RCW 41.05.410 and 2021 c 246 s 6 are each amended to
8 read as follows:

9 (1) The authority, in consultation with the health benefit
10 exchange, must contract with one or more health carriers to offer
11 qualified health plans on the Washington health benefit exchange for
12 plan years beginning in 2021. A health carrier contracting with the
13 authority under this section must offer at least one bronze, one
14 silver, and one gold qualified health plan in a single county or in
15 multiple counties. The goal of the procurement conducted under this
16 section is to have a choice of qualified health plans under this
17 section offered in every county in the state. The authority may not
18 execute a contract with an apparently successful bidder under this
19 section until after the insurance commissioner has given final
20 approval of the health carrier's rates and forms pertaining to the
21 health plan to be offered under this section and certification of the
22 health plan under RCW 43.71.065.

23 (2) A qualified health plan offered under this section must meet
24 the following criteria:

25 (a) The qualified health plan must be a standardized health plan
26 established under RCW 43.71.095;

27 (b) The qualified health plan must meet all requirements for
28 qualified health plan certification under RCW 43.71.065 including,
29 but not limited to, requirements relating to rate review and network
30 adequacy;

31 (c) The qualified health plan must incorporate recommendations of
32 the Robert Bree collaborative and the health technology assessment
33 program;

34 (d) The qualified health plan may use an integrated delivery
35 system or a managed care model that includes care coordination or
36 care management to enrollees as appropriate;

37 (e) The qualified health plan must meet additional participation
38 requirements to reduce barriers to maintaining and improving health
39 and align to state agency value-based purchasing. These requirements

1 may include, but are not limited to, standards for population health
2 management; high-value, proven care; health equity; primary care;
3 care coordination and chronic disease management; wellness and
4 prevention; prevention of wasteful and harmful care; and patient
5 engagement;

6 (f) To reduce administrative burden and increase transparency,
7 the qualified health plan's utilization review processes must:

8 (i) Be focused on care that has high variation, high cost, or low
9 evidence of clinical effectiveness; and

10 (ii) Meet national accreditation standards;

11 (g) The total amount the qualified health plan reimburses
12 providers and facilities for all covered benefits in the statewide
13 aggregate, excluding pharmacy benefits, may not exceed one hundred
14 sixty percent of the total amount medicare would have reimbursed
15 providers and facilities for the same or similar services in the
16 statewide aggregate;

17 (h) For services provided by rural hospitals certified by the
18 centers for medicare and medicaid services as critical access
19 hospitals or sole community hospitals, the rates may not be less than
20 one hundred one percent of allowable costs as defined by the United
21 States centers for medicare and medicaid services for purposes of
22 medicare cost reporting;

23 (i) Reimbursement for primary care services, as defined by the
24 authority, provided by a physician with a primary specialty
25 designation of family medicine, general internal medicine, or
26 pediatric medicine, may not be less than one hundred thirty-five
27 percent of the amount that would have been reimbursed under the
28 medicare program for the same or similar services; and

29 (j) The qualified health plan must comply with any requirements
30 established by the authority to address amounts expended on pharmacy
31 benefits including, but not limited to, increasing generic and
32 biosimilar utilization and use of evidence-based formularies.

33 (3) (a) At the request of the authority for monitoring,
34 enforcement, or program and quality improvement activities, a
35 qualified health plan offered under this section must provide cost
36 and quality of care information and data to the authority, and may
37 not enter into an agreement with a provider or third party that would
38 restrict the qualified health plan from providing this information or
39 data.

1 (b) Pursuant to RCW 42.56.650, any cost or quality information or
2 data submitted to the authority is exempt from public disclosure.

3 (4) Nothing in this section prohibits a health carrier offering
4 qualified health plans under this section from offering other health
5 plans in the individual market.

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