
SENATE BILL 5594

State of Washington

69th Legislature

2025 Regular Session

By Senators Harris and Cleveland

1 AN ACT Relating to reducing prescription drug costs by
2 eliminating barriers impeding access to biosimilar medicines;
3 amending RCW 48.43.420, 41.05.410, 69.41.120, and 69.41.125; and
4 creating a new section.

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

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

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

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

18 (1) When coverage of a prescription drug for the treatment of any
19 medical condition is subject to prescription drug utilization
20 management, the patient and prescribing practitioner must have access

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

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

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

21 (a) The required prescription drug is contraindicated or will
22 likely cause a clinically predictable adverse reaction by 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 or
28 another prescription drug in the same pharmacologic class or a drug
29 with the same mechanism of action while under his or her current or a
30 previous health plan, and such prescription drug was discontinued due
31 to lack of efficacy or effectiveness, diminished effect, or an
32 adverse event;

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

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

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

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

7 (iii) Cause a clinically predictable negative drug
8 interaction; or

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

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

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

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

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

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

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

36 (ii) Within one business day of receipt of sufficient information
37 from the treating health care provider as disclosed under subsection
38 (2) of this section, approve a request if the information provided
39 meets at least one of the conditions referenced in subsection (3) of
40 this section or if deemed medically appropriate, or deny a request if

1 the requested service does not meet at least one of the conditions
2 referenced in subsection (3) of this section.

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

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

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

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

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

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

37 (10) This section does not prevent:

38 (a) A health carrier or prescription drug utilization management
39 entity from requiring a patient to try an AB-rated generic equivalent
40 (~~(or a biological product that is)~~) an interchangeable biological

1 product, or a biosimilar as defined under 42 U.S.C. Sec. 262 (i)(2),
2 prior to providing coverage for the equivalent branded prescription
3 drug;

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

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

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

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

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

28 (a) The qualified health plan must be a standardized health plan
29 established under RCW 43.71.095;

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

34 (c) The qualified health plan must incorporate recommendations of
35 the Robert Bree collaborative and the health technology assessment
36 program;

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

1 (e) The qualified health plan must meet additional participation
2 requirements to reduce barriers to maintaining and improving health
3 and align to state agency value-based purchasing. These requirements
4 may include, but are not limited to, standards for population health
5 management; high-value, proven care; health equity; primary care;
6 care coordination and chronic disease management; wellness and
7 prevention; prevention of wasteful and harmful care; and patient
8 engagement;

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

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

13 (ii) Meet national accreditation standards;

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

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

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

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

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

1 restrict the qualified health plan from providing this information or
2 data.

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

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

8 **Sec. 4.** RCW 69.41.120 and 2015 c 242 s 2 are each amended to
9 read as follows:

10 (1) ~~((Every drug prescription shall contain an instruction on
11 whether or not a therapeutically equivalent generic drug or
12 interchangeable biological product may be substituted in its place,
13 unless substitution is permitted under a prior consent authorization.~~

14 ~~If a written prescription is involved, the prescription must be
15 legible and the form shall have two signature lines at opposite ends
16 on the bottom of the form. Under the line at the right side shall be
17 clearly printed the words "DISPENSE AS WRITTEN." Under the line at
18 the left side shall be clearly printed the words "SUBSTITUTION
19 PERMITTED." The practitioner shall communicate the instructions to
20 the pharmacist by signing the appropriate line. No prescription shall
21 be valid without the signature of the practitioner on one of these
22 lines. In the case of a prescription issued by a practitioner in
23 another state that uses a one-line prescription form or variation
24 thereof, the pharmacist may substitute a therapeutically equivalent
25 generic drug or interchangeable biological product unless otherwise
26 instructed by the practitioner through the use of the words "dispense
27 as written," words of similar meaning, or some other indication.~~

28 ~~(2) If an oral prescription is involved, the practitioner or the
29 practitioner's agent shall instruct the pharmacist as to whether or
30 not a therapeutically equivalent generic drug or interchangeable
31 biological product may be substituted in its place. The pharmacist
32 shall note the instructions on the file copy of the prescription.~~

33 ~~(3)) A pharmacist filling a prescription order for a drug
34 product prescribed by its trade or brand name may select a biosimilar
35 as defined under 42 U.S.C. Sec. 262 (i)(2), or interchangeable
36 biological product.~~

37 ~~(2) In no case shall a selection be made under this section if
38 the practitioner personally indicates, either orally or in the
39 practitioner's own handwriting, "do not substitute," "dispense as~~

1 written," or words of similar meaning. Nothing in this subsection
2 prohibits a practitioner from checking a box on a prescription marked
3 "do not substitute" if the practitioner personally initials the box
4 or checkmark.

5 (3) (a) Selection under this section is within the discretion of
6 the pharmacist, except as provided in subsection (2) of this section.
7 The person who selects the drug product to be dispensed under this
8 section assumes the same responsibility for selecting the dispensed
9 drug product as would be incurred in filling a prescription for a
10 drug product prescribed by generic name. There shall be no liability
11 on the practitioner for an act or omission by a pharmacist in
12 selecting, preparing, or dispensing a drug product under this
13 section. In no case shall the pharmacist select a drug product under
14 this section unless the drug product selected costs the patient less
15 than the prescribed drug product.

16 (b) For the purposes of this subsection, "cost" includes any
17 professional fee that may be charged by the pharmacist.

18 (4) When a substitution is made under this section, the intent of
19 the substitution should be to provide a product with a lower out-of-
20 pocket cost to the patient. The drug product dispensed must be
21 communicated to the patient with the name of the dispensed drug
22 product indicated on the prescription label.

23 (5) The pharmacist shall note the manufacturer of the drug
24 dispensed on the file copy of a written or oral prescription.

25 ~~((4))~~ (6) The pharmacist shall retain the file copy of a
26 written or oral prescription for the same period of time specified in
27 RCW 18.64.245 for retention of prescription records.

28 **Sec. 5.** RCW 69.41.125 and 2015 c 242 s 3 are each amended to
29 read as follows:

30 Unless the prescribed biological product is requested by the
31 patient or the patient's representative, ~~((if "substitution~~
32 ~~permitted" is marked on the prescription as provided in RCW~~
33 ~~69.41.120))~~ or the prescriber has indicated "do not substitute," or
34 words of similar meaning, the pharmacist must substitute ~~((an))~~ a
35 biosimilar as defined under 42 U.S.C. Sec. 262 (i)(2) or
36 interchangeable biological product that he or she has in stock for
37 the biological product prescribed if the wholesale price for the

1 biosimilar or interchangeable biological product to the pharmacist is
2 less than the wholesale price for the biological product prescribed.

--- **END** ---