
SECOND ENGROSSED SUBSTITUTE SENATE BILL 5594

State of Washington

69th Legislature

2025 Regular Session

By Senate Health & Long-Term Care (originally sponsored by Senators Harris, Cleveland, Hasegawa, and Shewmake)

READ FIRST TIME 02/19/25.

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

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

6 **Sec. 1.** RCW 48.43.420 and 2019 c 171 s 3 are each amended to
7 read as follows:

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

10 (1) When coverage of a prescription drug for the treatment of any
11 medical condition is subject to prescription drug utilization
12 management, the patient and prescribing practitioner must have access
13 to a clear, readily accessible, and convenient process to request an
14 exception through which the prescription drug utilization management
15 can be overridden in favor of coverage of a prescription drug
16 prescribed by a treating health care provider. A health carrier or
17 prescription drug utilization management entity may use its existing
18 medical exceptions process to satisfy this requirement. The process
19 must be easily accessible on the health carrier and prescription drug
20 utilization management entity's website. Approval criteria must be
21 clearly posted on the health carrier and prescription drug

1 utilization management entity's website. This information must be in
2 plain language and understandable to providers and patients.

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

8 (3) An exception request must be granted if the health carrier or
9 prescription drug utilization management entity determines that the
10 evidence submitted by the provider or patient is sufficient to
11 establish that:

12 (a) The required prescription drug is contraindicated or will
13 likely cause a clinically predictable adverse reaction by the
14 patient;

15 (b) The required prescription drug is expected to be ineffective
16 based on the known clinical characteristics of the patient and the
17 known characteristics of the prescription drug regimen;

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

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

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

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

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

36 (iii) Cause a clinically predictable negative drug
37 interaction; or

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

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

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

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

12 (ii) Within three business days of receipt of sufficient
13 information from the treating health care provider as disclosed under
14 subsection (2) of this section, approve a request if the information
15 provided meets at least one of the conditions referenced in
16 subsection (3) of this section or if deemed medically appropriate, or
17 deny a request if the requested service does not meet at least one of
18 the conditions referenced in subsection (3) of this section.

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

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

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

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

37 (d) For purposes of this subsection, exception requests are
38 considered urgent when an enrollee is experiencing a health condition
39 that may seriously jeopardize the enrollee's life, health, or ability

1 to regain maximum function, or when an enrollee is undergoing a
2 current course of treatment using a nonformulary drug.

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

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

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

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

28 (10) This section does not prevent:

29 (a) A health carrier or prescription drug utilization management
30 entity from requiring a patient to try an AB-rated generic equivalent
31 or a biological product that is an interchangeable biological product
32 prior to providing coverage for the equivalent branded prescription
33 drug;

34 (b) Beginning January 1, 2027, a health carrier or prescription
35 drug utilization management entity from requiring a patient to try a
36 biosimilar prior to providing coverage for the equivalent branded
37 prescription drug;

38 (c) A health carrier or prescription drug utilization management
39 entity from denying an exception for a drug that has been removed

1 from the market due to safety concerns from the federal food and drug
2 administration; or

3 ~~((e))~~ (d) A health care provider from prescribing a
4 prescription drug that is determined to be medically appropriate.

5 **Sec. 2.** RCW 41.05.410 and 2021 c 246 s 6 are each amended to
6 read as follows:

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

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

23 (a) The qualified health plan must be a standardized health plan
24 established under RCW 43.71.095;

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

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

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

35 (e) The qualified health plan must meet additional participation
36 requirements to reduce barriers to maintaining and improving health
37 and align to state agency value-based purchasing. These requirements
38 may include, but are not limited to, standards for population health
39 management; high-value, proven care; health equity; primary care;

1 care coordination and chronic disease management; wellness and
2 prevention; prevention of wasteful and harmful care; and patient
3 engagement;

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

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

8 (ii) Meet national accreditation standards;

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

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

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

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

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

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

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

4 **Sec. 3.** RCW 69.41.120 and 2015 c 242 s 2 are each amended to
5 read as follows:

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

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

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

29 ~~(3)) A pharmacist may substitute a therapeutically equivalent
30 drug or interchangeable biological product unless otherwise
31 instructed by the practitioner through the use of words "dispense as
32 written," words of a similar meaning, or some other equivalent
33 indication.~~

34 (2) If an oral prescription is involved, a pharmacist may
35 substitute a therapeutically equivalent generic drug or
36 interchangeable biological product in its place unless the
37 practitioner or the practitioner's agent instructs the pharmacist not
38 to substitute. The pharmacist shall note the instructions on the file
39 copy of the prescription.

1 (3) The pharmacist shall note the manufacturer of the drug
2 dispensed on the file copy of a written or oral prescription, unless
3 this information is maintained in a separate record that is readily
4 retrievable by the pharmacist.

5 (4) The pharmacist shall retain the file copy of a written or
6 oral prescription for the same period of time specified in RCW
7 18.64.245 for retention of prescription records.

8 **Sec. 4.** RCW 69.41.125 and 2015 c 242 s 3 are each amended to
9 read as follows:

10 Unless the prescribed biological product is requested by the
11 patient or the patient's representative, ~~((if "substitution~~
12 ~~permitted" is marked on the prescription as provided in RCW~~
13 ~~69.41.120))~~ or the prescriber has indicated substitution is not
14 permitted in accordance with RCW 69.41.120, the pharmacist ((must))
15 may substitute an interchangeable biological product that he or she
16 has in stock for the biological product prescribed if the ((wholesale
17 price for the interchangeable biological product to the pharmacist is
18 less than the wholesale price)) consumer's out-of-pocket cost for the
19 interchangeable biological product is less than the consumer's out-
20 of-pocket cost for the biological product prescribed.

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