S-1619.2

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) This section does not prevent:

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

prior to providing coverage for the equivalent branded prescription drug;

(b) Beginning January 1, 2026, a health carrier or prescription drug utilization management entity from requiring a patient to try a biosimilar prior to providing coverage for the equivalent branded prescription drug;

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Meet national accreditation standards;

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

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

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

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

(3)(a) At the request of the authority for monitoring, enforcement, or program and quality improvement activities, a

qualified health plan offered under this section must provide cost and quality of care information and data to the authority, and may not enter into an agreement with a provider or third party that would restrict the qualified health plan from providing this information or data.

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

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

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

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

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

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

~~(3)~~)) (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug

name as determined by the United States adopted name council and accepted by the federal food and drug administration, of those drug products having the same active chemical ingredients.

(b) A pharmacist filling a prescription order for a biological product prescribed by its trade or brand name may select an interchangeable biological product.

(2) In no case shall a selection be made under this section if the practitioner personally indicates, either orally or in the practitioner's own handwriting, "do not substitute," "dispense as written," or words of similar meaning. Nothing in this subsection prohibits a practitioner from checking a box on a prescription marked "do not substitute" if the practitioner personally initials the box or checkmark.

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

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

(4) When a substitution is made under this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug or biological product shall be indicated on the prescription label, except where the practitioner orders otherwise.

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

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

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

Unless the prescribed biological product is requested by the patient or the patient's representative, ((~~if "substitution permitted" is marked on the prescription as provided in RCW 69.41.120~~)) or the prescriber has indicated "do not substitute," or words of similar meaning, the pharmacist must substitute an interchangeable biological product that he or she has in stock for the biological product prescribed if the wholesale price for the interchangeable biological product to the pharmacist is less than the wholesale price for the biological product prescribed.

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