
HOUSE BILL 2613

State of Washington

69th Legislature

2026 Regular Session

By Representatives Thai, Parshley, Duerr, Santos, Ormsby, and Hill

Read first time 01/21/26. Referred to Committee on Health Care & Wellness.

1 AN ACT Relating to establishing safety and regulatory
2 requirements for compounded medications; adding a new section to
3 chapter 18.64 RCW; creating new sections; prescribing penalties; and
4 declaring an emergency.

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

6 NEW SECTION. **Sec. 1.** (1) The legislature finds that:

7 (a) The safety and integrity of compounded medications are
8 paramount to the health and well-being of residents of Washington;

9 (b) The federal food and drug administration sets internationally
10 recognized standards for drug approval and regulatory oversight;
11 however, there have been increasing attempts by unscrupulous actors
12 to circumvent these regulations, undermining public trust and patient
13 safety;

14 (c) Foreign entities, including those from countries such as
15 China, have exploited regulatory gaps to introduce inferior or
16 contaminated active pharmaceutical ingredients into the supply chain
17 for medications intended for compounding;

18 (d) Recent cases, such as those involving medications for weight
19 loss, have demonstrated that high demand can lead to the
20 proliferation of use of illicit, substandard, and potentially harmful

1 active pharmaceutical ingredients, jeopardizing patient health and
2 safety;

3 (e) While the food and drug administration bears responsibility
4 for enforcing federal laws to protect citizens from misbranded and
5 adulterated pharmaceutical ingredients, enforcement has proven
6 insufficient to curtail the influx of these substances; and

7 (f) Even after the federal food and drug administration took some
8 action to curb imports of active pharmaceutical ingredients for
9 weight loss medications from entities that are not compliant with
10 current good manufacturing practice requirements, patients in our
11 state remain at risk of receiving compounded medications containing
12 active pharmaceutical ingredients produced by entities that the food
13 and drug administration found to not be compliant with those
14 requirements, including active pharmaceutical ingredients imported
15 into the United States before the food and drug administration took
16 action.

17 (2) The legislature finds that it is necessary for the state to
18 take action to protect its residents by ensuring that all active
19 pharmaceutical ingredients used in compounding are sourced from
20 reputable, registered, and inspected establishments, and that only
21 pharmaceutical-grade, safe, and pure ingredients are utilized in
22 medications for weight loss.

23 NEW SECTION. **Sec. 2.** A new section is added to chapter 18.64
24 RCW to read as follows:

25 (1) It is unlawful for any person or entity to engage in the
26 sale, transfer, or distribution of a drug compounded under section
27 503A of the federal food, drug, and cosmetic act, 21 U.S.C. Sec.
28 353a, unless the compounder of the drug:

29 (a) Uses bulk drug substances that:

30 (i) Comply with the standards of an applicable United States
31 pharmacopoeia or national formulary monograph, if a monograph exists,
32 and the United States pharmacopoeia chapter on pharmacy compounding;

33 (ii) If a monograph described in (a)(i) of this subsection (1)
34 does not exist, are drug substances that are components of drugs
35 approved by the federal food and drug administration; or

36 (iii) If a monograph described in (a)(i) of this subsection (1)
37 does not exist and the drug substance is not a component of a drug
38 approved by the federal food and drug administration, appear on the
39 list developed by the federal food and drug administration pursuant

1 to section 503A(b)(1)(A)(i)(III) of the federal food, drug, and
2 cosmetic act, 21 U.S.C. Sec. 353a(b)(1)(A)(i)(III);

3 (b) Confirms that any bulk drug substance used under subsection
4 (1)(a)(ii) of this section was reviewed as part of a new drug
5 application approved by the federal food and drug administration
6 under section 505 of the federal food, drug, and cosmetic act, 21
7 U.S.C. Sec. 355;

8 (c) Ensures that the bulk drug substance is a pharmaceutical
9 grade product;

10 (d) Verifies that the bulk drug substance is accompanied by a
11 valid certificate of analysis containing all information material to
12 the safety and effectiveness of the drug compounded using the bulk
13 drug substance, including the identity and content of the bulk drug
14 substance, the country where the bulk drug substance was originally
15 manufactured, identification of each impurity by chemical name and
16 amount present, and any additional element that the commission may
17 require by regulation;

18 (e) Conducts and documents quality control testing of the bulk
19 drug substance prior to its use in a compounded drug to confirm:

20 (i) The identity and content of the bulk drug substance; and

21 (ii) That impurities present are identified, characterized,
22 quantified, and justified given the product and its intended use;

23 (f) Obtains proof that the manufacture of the bulk drug substance
24 took place in an establishment that:

25 (i) Is duly registered for the federal food and drug
26 administration under section 510 of the federal food, drug, and
27 cosmetic act, 21 U.S.C. Sec. 360; and

28 (ii) Has undergone an inspection within the last two years by the
29 federal food and drug administration as a human drug establishment
30 and the inspection:

31 (A) Included current good manufacturing practice compliance and
32 covered the relevant bulk drug substance; and

33 (B) Was classified as "voluntary action indicated" or "no action
34 indicated"; and

35 (g) Complies with the federal food, drug, and cosmetic act,
36 including the provisions in section 503A, 21 U.S.C. Sec. 353a.

37 (2)(a) Any person or entity engaging in the sale, transfer, or
38 distribution of compounded drugs shall maintain all records related
39 to the acquisition, examination, and testing of the bulk drug
40 substance for not less than two years after the expiration date of

1 the last lot of drug containing the bulk drug substance and, upon a
2 request by the commission, shall furnish such records within one
3 business day of receiving the request, or within a reasonable time as
4 determined by the commission based on the circumstances of the
5 request.

6 (b) The commission, its duly authorized agent, or a duly
7 authorized agent of a third party approved by the commission, shall
8 have the authority to inspect any person or entity that engages in
9 compounding drugs, as well as any domestic supplier, wholesaler,
10 repackager, or other provider of the bulk drug substance for
11 compounding, for compliance with the requirements in subsection (1)
12 of this section. Refusal to permit the commission, its duly
13 authorized agent, or third party, access to conduct an inspection
14 shall constitute a violation of this section.

15 (3) A violation of this section shall result in:

16 (a) A fine of \$1,000 per dose of the illegally compounded drug
17 sold, transferred, or distributed; and

18 (b) Revocation of the pharmacy license.

19 (4) The commission may adopt rules to implement this section.

20 (5) For the purposes of this section, the terms "bulk drug
21 substance" or "active pharmaceutical ingredient" mean any substance
22 that is intended for incorporation into a finished drug product and
23 is intended to furnish pharmacological activity or other direct
24 effect in the diagnosis, cure, mitigation, treatment, or prevention
25 of disease, or to affect the structure or any function of the body.
26 It does not include intermediates used in the synthesis of the
27 substance.

28 NEW SECTION. **Sec. 3.** If any part of this act is found to be in
29 conflict with federal requirements that are a prescribed condition to
30 the allocation of federal funds to the state, the conflicting part of
31 this act is inoperative solely to the extent of the conflict and with
32 respect to the agencies directly affected, and this finding does not
33 affect the operation of the remainder of this act in its application
34 to the agencies concerned. Rules adopted under this act must meet
35 federal requirements that are a necessary condition to the receipt of
36 federal funds by the state.

37 NEW SECTION. **Sec. 4.** This act is necessary for the immediate
38 preservation of the public peace, health, or safety, or support of

1 the state government and its existing public institutions, and takes
2 effect immediately.

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