

119TH CONGRESS
1ST SESSION

H. R. 6509

To amend the Federal Food, Drug, and Cosmetic Act to further regulate compounding pharmacies and outsourcing facilities, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 9, 2025

Mr. YAKYM (for himself and Mr. CARSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to further regulate compounding pharmacies and outsourcing facilities, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safeguarding Ameri-
5 cans from Fraudulent and Experimental Drugs Act of
6 2025” or the “SAFE Drugs Act of 2025”.

7 **SEC. 2. DEFINITIONS RELATING TO COMPOUNDING OF**
8 **DRUG PRODUCTS.**

9 Section 503A(b) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 353a(b)) is amended—

1 (1) by amending paragraph (1)(D) to read as
2 follows:

3 “(D) does not, more than 20 times in a
4 single month, compound any drug product that
5 is essentially a copy of a commercially available
6 drug product.”; and

7 (2) by amending paragraph (2) to read as fol-
8 lows:

9 “(2) DEFINITIONS.—

10 “(A) For purposes of paragraph (1)(D),
11 the term ‘essentially a copy of a commercially
12 available drug product’ means any drug prod-
13 uct—

14 “(i) that contains any active ingre-
15 dient found in a commercially available
16 drug product; and

17 “(ii) in which there is no change,
18 made for an identified individual patient,
19 which produces for that patient a signifi-
20 cant difference, as determined by the pre-
21 scribing practitioner, between the com-
22 pounded drug product and the comparable
23 commercially available drug product.

1 “(B) For purposes of subparagraph (A),
 2 the term ‘commercially available drug product’
 3 includes any drug product that—

4 “(i) is sold in the commercial market-
 5 place in the United States and manufac-
 6 tured in one or more facilities required to
 7 comply with section 501(a)(2)(B); and

8 “(ii) is not included in the discon-
 9 tinued section of the list of products de-
 10 scribed in section 505(j)(7)(A).”.

11 **SEC. 3. REPORTING REQUIREMENT.**

12 Section 503A of the Federal Food, Drug, and Cos-
 13 metic Act (21 U.S.C. 353a) is amended—

14 (1) by redesignating subsections (d) and (e) as
 15 subsections (e) and (f), respectively; and

16 (2) by inserting after subsection (c) the fol-
 17 lowing:

18 “(d) REPORTING REQUIREMENT.—

19 “(1) IN GENERAL.—For calendar year 2025
 20 and each calendar year thereafter, if a pharmacy, fa-
 21 cility, or physician compounds, more than 20 times
 22 in a single month for patients who reside outside the
 23 State in which the compounding occurs, any drug
 24 product that contains any active ingredient found in
 25 a commercially available drug product (as defined in

1 subsection (b)(2)(B)), such pharmacy, facility, or
 2 physician shall submit a report to the Secretary.

3 “(2) CONTENTS.—Each report under para-
 4 graph (1) shall identify—

5 “(A) each type of drug product described
 6 in paragraph (1) that is compounded for a pa-
 7 tient described in such paragraph; and

8 “(B) for each month, the total number of
 9 times each such type is so compounded.

10 “(3) TIMING.—For any calendar year for which
 11 paragraph (1) applies, the pharmacy, facility, or
 12 physician shall submit the report under such para-
 13 graph not later than the end of such calendar year.

14 “(4) FORM AND MANNER.—A pharmacy, facil-
 15 ity, or physician shall submit each report under
 16 paragraph (1) in such form and manner as the Sec-
 17 retary may prescribe.

18 “(5) HOSPITAL PHARMACY EXCLUSION.—This
 19 subsection does not apply to the compounding of any
 20 drug products for hospital patients by a pharmacy
 21 located on the premises of the hospital.”.

22 **SEC. 4. LARGE-SCALE OUTSOURCING FACILITIES.**

23 (a) INSPECTIONS.—Section 503B(b) of the Federal
 24 Food, Drug, and Cosmetic Act (21 U.S.C. 353b(b)) is
 25 amended by adding at the end the following:

1 “(6) INSPECTIONS OF LARGE-SCALE OUTSOURC-
2 ING FACILITIES.—

3 “(A) IN GENERAL.—In the case of a large-
4 scale outsourcing facility, the risk-based inspec-
5 tions under paragraph (4) shall include—

6 “(i) an inspection prior to such facil-
7 ity compounding any drug product for the
8 first time; and

9 “(ii) the reinspection of such facility
10 not less than biennially.

11 “(B) LARGE-SCALE OUTSOURCING FACIL-
12 ITY DEFINED.—For purposes of this paragraph,
13 the term ‘large-scale outsourcing facility’ means
14 any outsourcing facility that compounds, more
15 than 100 times in a single calendar year, any
16 drug product.”.

17 (b) REGISTRATION AND REPORTING REQUIRE-
18 MENT.—Section 510(g)(1) of such Act (21 U.S.C.
19 360(g)(1)) is amended by inserting before the semicolon
20 at the end the following: “, except that the exemption in
21 this paragraph shall not apply to any outsourcing facility
22 (as defined in section 503B(d)(4))”.

23 (c) DELAYED APPLICABILITY.—The amendments
24 made by subsections (a) and (b) apply beginning 6 months
25 after the date of enactment of this Act.

1 **SEC. 5. BASE ESTABLISHMENT FEE.**

2 Section 744K(c)(1)(A)(i) of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 379j–62(c)(1)(A)(i)) is
4 amended by striking “\$15,000” and inserting “a base
5 amount deemed appropriate by the Secretary to fund ac-
6 tivities to ensure the safety of compounded drug prod-
7 ucts”.

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