

Calendar No. 524

119TH CONGRESS
2D SESSION**S. 3794**

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 5, 2026

Mr. BANKS (for himself and Mr. HEINRICH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 27, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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 2026” or the “SAFE Drugs Act of 2026”.

1 **SEC. 2. DEFINITIONS RELATING TO COMPOUNDING OF**
 2 **DRUG PRODUCTS.**

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

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

7 “(D) does not, more than 20 times in a
 8 single month, compound any drug product that
 9 is essentially a copy of a commercially available
 10 drug product.”; and

11 (2) by amending paragraph (2) to read as fol-
 12 lows:

13 “(2) DEFINITIONS.—

14 “(A) For purposes of paragraph (1)(D),
 15 the term ‘essentially a copy of a commercially
 16 available drug product’ means any drug prod-
 17 uct—

18 “(i) that contains any active ingre-
 19 dient found in a commercially available
 20 drug product; and

21 “(ii) in which there is no change,
 22 made for an identified individual patient,
 23 which produces for that patient a signifi-
 24 cant difference, as determined by the pre-
 25 scribing practitioner, between the com-

pounded drug product and the comparable
commercially available drug product.

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

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

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

SEC. 3. REPORTING REQUIREMENT.

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

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

(2) by inserting after subsection (e) the fol-
lowing:

“(d) REPORTING REQUIREMENT.—

“(1) IN GENERAL.—For calendar year 2025
and each calendar year thereafter, if a pharmacy, fa-
cility, or physician compounds, more than 20 times
in a single month for patients who reside outside the
State in which the compounding occurs, any drug

1 product that contains any active ingredient found in
2 a commercially available drug product (as defined in
3 subsection (b)(2)(B)), such pharmacy, facility, or
4 physician shall submit a report to the Secretary.

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

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

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

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

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

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

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

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

5 “(6) ~~INSPECTIONS OF LARGE-SCALE OUTSOURC-~~
6 ~~ING FACILITIES.~~—

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

10 “(i) an inspection prior to such facil-
11 ity compounding any drug product for the
12 first time; and

13 “(ii) the reinspection of such facility
14 not less than biennially.

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

21 (b) ~~REGISTRATION AND REPORTING REQUIRE-~~
22 ~~MENT.~~—Section 510(g)(1) of such Act (21 U.S.C.
23 360(g)(1)) is amended by inserting before the semicolon
24 at the end the following: “, except that the exemption in
25 this paragraph shall not apply to any outsourcing facility
26 (as defined in section 503B(d)(4))”.

1 ~~(e) DELAYED APPLICABILITY.—~~The amendments
 2 made by subsections (a) and (b) apply beginning 6 months
 3 after the date of enactment of this Act.

4 **SEC. 5. BASE ESTABLISHMENT FEE.**

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

11 **SECTION 1. SHORT TITLE.**

12 *This Act may be cited as the “Safeguarding Americans*
 13 *from Fraudulent and Experimental Drugs Act of 2026” or*
 14 *the “SAFE Drugs Act of 2026”.*

15 **SEC. 2. REPORTING REQUIREMENT.**

16 *Section 503A of the Federal Food, Drug, and Cosmetic*
 17 *Act (21 U.S.C. 353a) is amended—*

18 *(1) by redesignating subsections (d) and (e) as*
 19 *subsections (e) and (f), respectively; and*

20 *(2) by inserting after subsection (c) the fol-*
 21 *lowing:*

22 *“(d) REPORTING.—*

23 *“(1) SERIOUS ADVERSE EVENTS.—Each licensed*
 24 *pharmacist or licensed physician who compounds*
 25 *drug products under this section and sends such drug*

1 *products, or causes such drug products to be sent, out*
 2 *of the State in which the compounding occurs shall*
 3 *submit any report received by such licensed phar-*
 4 *macist or licensed physician of a serious adverse event*
 5 *associated with a compounded drug product, in ac-*
 6 *cordance with the content and format requirements*
 7 *established through guidance or under section 310.305*
 8 *of title 21, Code of Federal Regulations (or any suc-*
 9 *cessor regulations), to—*

10 “(A) *the Secretary;*

11 “(B) *the State in which the compounding*
 12 *occurs; and*

13 “(C) *each State to which such drugs are*
 14 *sent.*

15 “(2) *INTERSTATE DISPENSING.—*

16 “(A) *IN GENERAL.—Beginning with the*
 17 *first calendar year that begins after the date of*
 18 *enactment of the SAFE Drugs Act of 2026, not*
 19 *later than January 15 of each calendar year,*
 20 *each licensed pharmacist or licensed physician*
 21 *who compounds drug products under this section*
 22 *and sends, or causes to be sent, out of the State*
 23 *in which the compounding occurs, more than 5*
 24 *percent of the total annual amount of drug prod-*
 25 *ucts compounded by such licensed pharmacist or*

1 *licensed physician shall annually submit a re-*
 2 *port containing the information described in*
 3 *subparagraph (B) to the Secretary and the State*
 4 *to which such drug products are sent.*

5 “(B) *CONTENTS.*—*Each report under sub-*
 6 *paragraph (A) shall identify—*

7 “(i) *the name, address, license number,*
 8 *and State of license of the licensed phar-*
 9 *macist or licensed physician who com-*
 10 *pounded the drug product; and*

11 “(ii) *the total number of units of com-*
 12 *pounded drug products, by type of product,*
 13 *and by month, sent or caused to be sent to*
 14 *each applicable State.*

15 “(C) *FORM AND MANNER.*—*A licensed phar-*
 16 *macist or licensed physician shall submit each*
 17 *report under subparagraph (A) in such form and*
 18 *manner as the Secretary may prescribe.*

19 “(D) *INFORMATION SHARING.*—*The Sec-*
 20 *retary shall use an information sharing system*
 21 *for purposes of facilitating the transmission of*
 22 *reports under subparagraph (A) from a licensed*
 23 *pharmacist or licensed physician to the Sec-*
 24 *retary and each applicable State in a manner*
 25 *that reduces unnecessary administrative burden.*

1 “(E) *EXCLUSION.*—*This subsection shall not*
 2 *apply to the compounding of any drug products*
 3 *for hospital patients by a pharmacy located on*
 4 *the premises of the hospital.*

5 “(3) *RULE OF CONSTRUCTION.*—*Nothing in this*
 6 *section shall be construed to preempt any requirement*
 7 *of a State or political subdivision of a State that re-*
 8 *quires additional, more stringent, or supplementary*
 9 *reporting with respect to a drug product compounded*
 10 *under this section.”.*

11 **SEC. 3. LABELING.**

12 *Section 503A(b)(3) of the Federal Food, Drug, and*
 13 *Cosmetic Act (21 U.S.C. 353a(b)(3)) is amended—*

14 (1) *in subparagraph (A), by striking “; and”*
 15 *and inserting a semicolon;*

16 (2) *in subparagraph (B)(ii), by striking the pe-*
 17 *riod and inserting “; and”; and*

18 (3) *by inserting after subparagraph (B) the fol-*
 19 *lowing:*

20 “(C) *the label of such drug product in-*
 21 *cludes—*

22 “(i) *the statement: ‘This medication*
 23 *has been compounded for dispensing to an*
 24 *individual patients and has not been ap-*

1 *proved by the Food and Drug Administra-*
2 *tion.’;*

3 *“(ii) the following information to fa-*
4 *cilitate adverse event reporting:*
5 *www.fda.gov/medwatch, and 1–800–FDA–*
6 *1088 (or any successor website or telephone*
7 *number); and*

8 *“(iii) such other information as the*
9 *Secretary may prescribe by order, which*
10 *may include information to facilitate ad-*
11 *verse event reporting.”.*

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