

113TH CONGRESS
1ST SESSION

H. R. 3019

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to enhance the requirements for pharmacies that compound drug products.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2013

Ms. DELAURO (for herself, Mrs. LOWEY, Mr. CONYERS, Mr. HONDA, and Mr. ELLISON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to enhance the requirements for pharmacies that compound drug products.

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 “Supporting Access to
5 Formulated and Effective Compounded Drugs Act of
6 2013” or the “S.A.F.E. Compounded Drugs Act of 2013”.

1 **SEC. 2. ENHANCED REQUIREMENTS FOR COMPOUNDED**
2 **DRUGS.**

3 (a) IN GENERAL.—Section 503A of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is
5 amended—

6 (1) in subsection (a)(1)(A), by inserting “that
7 is registered with the Secretary under subsection
8 (b)(6) (or is subject to the exception under sub-
9 section (b)(6)(C))” after “State licensed pharmacy”;

10 (2) in subsection (b)—

11 (A) in paragraph (1)(A), by inserting
12 “(meaning not more than 5 percent of the total
13 quantity of drugs products compounded by the
14 pharmacist or physician in any 30 day period)”
15 after “limited quantities”;

16 (B) in paragraph (1)(C), by striking “and”
17 at the end;

18 (C) in paragraph (1)(D), by striking “reg-
19 ularly or in inordinate amounts (as defined by
20 the Secretary)”;

21 (D) by adding at the end of paragraph (1)
22 the following:

23 “(E) does not compound a drug product
24 that appears on the list promulgated by the
25 Secretary under subsection (h); and

1 “(F) does not compound a drug product in
2 violation of the minimum standards promul-
3 gated under subsection (i).”; and

4 (E) by adding at the end of the subsection
5 the following:

6 “(4) NOTIFICATION.—

7 “(A) PRESCRIBER NOTIFICATION.—Before
8 providing a prescription order for a drug to be
9 compounded under subsection (a), the physician
10 or other licensed practitioner who will write
11 such order shall—

12 “(i) inform the individual patient for
13 whom such order is being written that a
14 compounded drug is being prescribed; and

15 “(ii) provide such patient with a writ-
16 ten document containing information con-
17 cerning the availability, safety, and produc-
18 tion of compounded drugs.

19 “(B) CONFIRMATION BY PHARMACIST.—
20 Except in the case of a compounded drug prod-
21 uct used in a procedure described in subpara-
22 graph (C), a licensed pharmacist or licensed
23 physician who dispenses a compounded drug
24 under subsection (a) shall, at the time such
25 drug is dispensed—

1 “(i) confirm that the patient (or the
2 individual to whom the drug is delivered on
3 behalf of the patient) understands that the
4 drug is a compounded drug; and

5 “(ii) provide a written document con-
6 taining the information described in sub-
7 paragraph (A)(ii).

8 “(C) PROVIDER NOTIFICATION.—Prior to
9 providing a health care service that will be con-
10 ducted by a health care provider in a health
11 care setting (such as a hospital or a physician’s
12 office) and during which service a drug com-
13 pounded under subsection (a) will be adminis-
14 tered to a patient for purposes of treating such
15 patient, the health care provider shall—

16 “(i) inform the patient that a com-
17 pounded drug will be used during the pro-
18 cedure; and

19 “(ii) provide such patient with a writ-
20 ten document containing the information
21 described in subparagraph (A)(ii).

22 “(5) LABELING.—

23 “(A) IN GENERAL.—A drug product com-
24 pounded under subsection (a) shall be clearly

1 labeled as a ‘non-FDA approved compounded
2 drug product’.

3 “(B) DEVELOPMENT OF REQUIRE-
4 MENTS.—In determining the requirements for
5 the label under subparagraph (A), the Sec-
6 retary—

7 “(i) shall establish, and consult with,
8 a temporary advisory committee on com-
9 pounded drug product labeling require-
10 ments; and

11 “(ii) may establish different labeling
12 requirements for—

13 “(I) a compounded drug product
14 intended for use by a health care pro-
15 vider in an office or treatment setting;
16 and

17 “(II) a compounded drug product
18 intended for any use not described in
19 subclause (I).

20 “(6) REGISTRATION.—

21 “(A) ESTABLISHMENT OF PROCESS.—The
22 Secretary, in consultation with experts and rep-
23 resentatives of stakeholders including phar-
24 macies, compounding pharmacies, State regu-
25 lators, and health care providers, shall establish

1 a process for pharmacies described in sub-
2 section (a)(1)(A) to register as a compounding
3 pharmacy. Such registration shall be conducted
4 through an electronic method.

5 “(B) REGISTRATION REQUIREMENT.—Ex-
6 cept as provided in subparagraph (C), in order
7 to be registered with the Secretary for purposes
8 of subsection (a)(1)(A), every person who owns
9 or operates a pharmacy shall submit to the Sec-
10 retary, in such time and manner as the Sec-
11 retary may require—

12 “(i) contact information for the phar-
13 macy;

14 “(ii) the State or States that the
15 pharmacy is licensed in;

16 “(iii) the methods used by the facility
17 in compounding; and

18 “(iv) any additional information re-
19 quired by the Secretary, which may include
20 the quantity of product compounded at
21 such pharmacy for the purpose of deter-
22 mining if a drug manufacturing facility is
23 inappropriately registering as a
24 compounding pharmacy.

1 “(C) PROHIBITION ON DUAL REGISTRA-
2 TION.—An entity registered under this sub-
3 section shall not be required to submit a reg-
4 istration under section 510.

5 “(D) EXCEPTION.—A pharmacy shall be
6 exempt from the requirement to register under
7 subsection (a)(1)(A) if the pharmacy—

8 “(i) employs fewer than 20 full-time
9 employees (or 20 full-time equivalents);
10 and

11 “(ii) performs traditional
12 compounding of drug products for use in a
13 single State.”; and

14 (3) by adding at the end of section 503A the
15 following:

16 “(g) DATABASE.—

17 “(1) IN GENERAL.—The Secretary shall estab-
18 lish and maintain a database of information on
19 pharmacies compounding drug products under sub-
20 section (a) that are licensed in more than one State,
21 including—

22 “(A) the minimum standards for a
23 compounding pharmacy license in each State;

1 “(B) relevant information provided to the
2 Secretary by State agencies that regulate phar-
3 macies;

4 “(C) reliable, timely, and comprehensive
5 data related to inspections of such pharmacies,
6 including the classification of actions indicated
7 as a result of such inspections; and

8 “(D) other information determined rel-
9 evant by the Secretary.

10 “(2) DESIGN.—The database under paragraph
11 (1)—

12 “(A) shall be accessible, as determined ap-
13 propriate by the Secretary, to State agencies
14 that regulate pharmacies that compound drug
15 products;

16 “(B) shall enable States and the Secretary
17 to share information to ensure appropriate
18 oversight of pharmacies that compound drug
19 products;

20 “(C) shall be used by the Secretary to in-
21 form the Federal inspection and oversight of
22 pharmacies that compound drug products to en-
23 sure that issues and pharmacies identified in
24 the database receive appropriate oversight; and

1 “(D) shall be accessible, as determined ap-
2 propriate by the Secretary, to health care pro-
3 viders and consumers.

4 “(h) ACTIVE INGREDIENTS AND DOSAGE FORMS
5 THAT SHOULD NOT BE COMPOUNDED.—The Secretary
6 shall, after consultation with appropriate stakeholders (in-
7 cluding pharmacists, patient and public health advocacy
8 groups, manufacturers, and health care professionals),
9 promulgate a list of active ingredients and dosage forms
10 that should not be compounded, because the compounding
11 of such active ingredient or dosage form is reasonably like-
12 ly to present a risk to public health.

13 “(i) MINIMUM STANDARDS.—

14 “(1) IN GENERAL.—The Secretary shall pro-
15 mulgate minimum standards for the safe production
16 of compounded drug products under this section.

17 “(2) CONTENTS.—The standards under para-
18 graph (1) shall each specify—

19 “(A) the type of compounded drug prod-
20 ucts to which they apply; and

21 “(B) the intended route of administration.

22 “(j) TRAINING.—The Secretary shall conduct a series
23 of regional training opportunities for State agencies that
24 regulate pharmacies that compound drug products. These
25 training opportunities shall include information on the

1 minimum standards under subsection (i), sample inspec-
2 tion protocol, and recordkeeping to facilitate the inclusion
3 of State findings and inspections into the database under
4 subsection (g).”.

5 (b) DEADLINES AND ADVISORY COMMITTEES.—

6 (1) DEADLINE FOR ISSUANCE OF REGULA-
7 TIONS.—Not later than 18 months after the date of
8 enactment of this Act, the Secretary of Health and
9 Human Services shall issue regulations to imple-
10 ment—

11 (A) paragraphs (4) and (5) of section
12 503A(b) of the Federal Food, Drug, and Cos-
13 metic Act, as added by subsection (a); and

14 (B) subsection (g) of section 503A of such
15 Act.

16 (2) LABELING ADVISORY COMMITTEE.—

17 (A) ESTABLISHMENT.—The Secretary of
18 Health and Human Services shall establish an
19 advisory committee on labeling (as defined in
20 section 201 of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 321)) of compounded
22 drug products and shall consult such committee
23 in the development of the regulations under
24 paragraph (1)(A).

1 (B) MEMBERSHIP.—The advisory com-
2 mittee shall include representatives of patients
3 or consumers, health care providers,
4 compounding pharmacies, State agencies that
5 regulate compounding pharmacies, and at least
6 one member with expertise on clearly commu-
7 nicating information in such labeling of drugs.

8 (C) MEETINGS.—The advisory committee
9 shall hold an initial meeting not later than 6
10 months after the date of enactment of this Act.

11 (D) RECOMMENDATIONS.—Not later than
12 12 months after the date of enactment of this
13 Act, the advisory committee shall submit to the
14 Secretary of Health and Human Services rec-
15 ommendations on the regulations under para-
16 graph (1)(A), including recommendations on
17 the type of information and language that
18 should be included on the labels of drug prod-
19 ucts that are compounded pursuant to section
20 503A of the Federal Food, Drug, and Cosmetic
21 Act.

22 (E) TERMINATION.—The advisory com-
23 mittee under this subparagraph shall terminate
24 upon the submission of the recommendations
25 under subparagraph (D).

1 (3) DATABASE ADVISORY COMMITTEE.—

2 (A) ESTABLISHMENT.—The Secretary of
3 Health and Human Services shall establish an
4 advisory committee on the database described
5 in section 503A(g) of the Federal Food, Drug,
6 and Cosmetic Act, as added by subsection (a),
7 and shall consult such committee in the devel-
8 opment of the regulations under paragraph
9 (1)(B).

10 (B) MEMBERSHIP.—The advisory com-
11 mittee shall include representatives of patients
12 or consumers, health care providers,
13 compounding pharmacies, State agencies that
14 regulate compounding pharmacies, and informa-
15 tion technology experts.

16 (C) MEETINGS.—The advisory committee
17 shall hold an initial meeting not later than 6
18 months after the date of enactment of this Act.

19 (D) RECOMMENDATIONS.—Not later than
20 12 months after the date of enactment of this
21 Act, the advisory committee shall submit to the
22 Secretary of Health and Human Services rec-
23 ommendations on the regulations under para-
24 graph (1)(B).

1 (E) TERMINATION.—The advisory com-
2 mittee under this subparagraph shall terminate
3 upon the submission of the recommendations
4 under subparagraph (D).

5 (4) PERMANENT ADVISORY COMMITTEE ON
6 PHARMACY COMPOUNDING.—The Secretary shall
7 convene the Advisory Committee on Pharmacy
8 Compounding as appropriate to consider issues re-
9 lated to the safety and availability of compounded
10 drug products.

11 **SEC. 3. REPORTS AND STUDIES.**

12 (a) BIENNIAL REPORTS.—Not later than 6 months
13 after the date of enactment of this Act, and at the end
14 of each succeeding 6-month period that ends before the
15 25th month after the date of enactment of this Act, the
16 Secretary of Health and Human Services shall submit to
17 the Congress a report on the status of the implementation
18 of the requirements of this Act, and the amendments made
19 by this Act.

20 (b) THIRD-PARTY ACCREDITATION.—Not later than
21 12 months after the date of enactment of this Act, the
22 Secretary shall submit to the Congress a report that con-
23 tains—

1 (1) a review of the standards used by organiza-
2 tions that provide accreditation to compounding
3 pharmacies; and

4 (2) an evaluation of the effectiveness of such
5 standards in ensuring the production of safe and ef-
6 fective compounded drug products.

7 (c) STRUCTURE OF STATE OVERSIGHT.—Not later
8 than 18 months after the date of enactment of this Act,
9 the Secretary shall submit to the Congress a report that
10 contains—

11 (1) a review of the models used by States to
12 structure their oversight of pharmacies that com-
13 pound drug products, including the structure of the
14 agency or office responsible for oversight and its re-
15 lationship with the industry that it regulates; and

16 (2) consideration of how the structure and rela-
17 tionship of State regulators may impact the develop-
18 ment and enforcement of regulations to ensure safe
19 compounded drug products.

20 (d) GAO REPORT.—The Comptroller General of the
21 United States shall review—

22 (1) the extent to which Federal health care pro-
23 grams (as such term is defined in section 1128B(f)
24 of the Social Security Act (42 U.S.C. 1320a–7b))
25 ensure that compounded drug products which are

1 paid for by such programs are compounded in facili-
2 ties that comply with the requirements of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301
4 et seq.);

5 (2) whether the reimbursement rates for com-
6 pounded drug products under such Federal health
7 care programs are appropriate, taking into consider-
8 ation the cost of production of such compounded
9 drug products; and

10 (3) whether such Federal health care programs
11 encourage the use of compounded drug products in
12 place of otherwise available lawfully marketed drug
13 products.

14 **SEC. 4. PROHIBITIONS AND PENALTIES.**

15 (a) PROHIBITION OF VIOLATIONS OF SECTION
16 503A.—Section 301(d) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 331(d)) is amended by inserting
18 “503A,” before “505,”.

19 (b) PENALTIES.—Section 303(b) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)) is
21 amended by adding at the end the following:

22 “(8) Notwithstanding subsection (a), any per-
23 son who violates section 301(d) with respect to any
24 compounded drug product—

1 “(A) knowingly and intentionally to de-
2 fraud or mislead; or
3 “(B) with conscious or reckless disregard
4 of a risk of death or serious bodily injury,
5 shall be fined under title 18, United States Code,
6 imprisoned for not more than 10 years, or both.”.

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