

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6638

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

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IN THE HOUSE OF REPRESENTATIVES

DECEMBER 5, 2012

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

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## 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        2012” or the “S.A.F.E. Compounded Drugs Act of 2012”.

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)(D), by striking “reg-  
12 ularly or in inordinate amounts (as defined by  
13 the Secretary)”; and

14 (B) by adding at the end the following:

15 “(4) NOTIFICATION.—

16 “(A) PRESCRIBER NOTIFICATION.—Before  
17 providing a prescription order for a drug to be  
18 compounded under subsection (a), the physician  
19 or other licensed practitioner who will write  
20 such order shall—

21 “(i) inform the individual patient for  
22 whom such order is being written that a  
23 compounded drug is being prescribed; and

24 “(ii) provide such patient with a writ-  
25 ten document containing information con-

1                   cerning the availability, safety, and produc-  
2                   tion of compounded drugs.

3                   “(B) CONFIRMATION BY PHARMACIST.—

4                   Except in the case of a compounded drug prod-  
5                   uct used in a procedure described in subpara-  
6                   graph (C), a licensed pharmacist or licensed  
7                   physician who dispenses a compounded drug  
8                   under subsection (a) shall, at the time such  
9                   drug is dispensed—

10                   “(i) confirm that the patient (or the  
11                   individual to whom the drug is delivered on  
12                   behalf of the patient) understands that the  
13                   drug is a compounded drug; and

14                   “(ii) provide a written document con-  
15                   taining the information described in sub-  
16                   paragraph (A)(ii).

17                   “(C) PROVIDER NOTIFICATION.—Prior to  
18                   providing a health care service that will be con-  
19                   ducted by a health care provider in a health  
20                   care setting (such as a hospital or a physician’s  
21                   office) and during which service a drug com-  
22                   pounded under subsection (a) will be adminis-  
23                   tered to a patient for purposes of treating such  
24                   patient, the health care provider shall—

1           “(i) inform the patient that a com-  
2           pounded drug will be used during the pro-  
3           cedure; and

4           “(ii) provide such patient with a writ-  
5           ten document containing the information  
6           described in subparagraph (A)(ii).

7           “(5) LABELING.—

8           “(A) IN GENERAL.—A drug product com-  
9           pounded under subsection (a) shall be clearly  
10          labeled as a ‘non-FDA approved compounded  
11          drug product’.

12          “(B) DEVELOPMENT OF REQUIRE-  
13          MENTS.—In determining the requirements for  
14          the label under subparagraph (A), the Sec-  
15          retary—

16                 “(i) shall establish, and consult with,  
17                 a temporary advisory committee on com-  
18                 pounded drug product labeling require-  
19                 ments; and

20                 “(ii) may establish different labeling  
21                 requirements for—

22                         “(I) a compounded drug product  
23                         intended for use by a health care pro-  
24                         vider in an office or treatment setting;  
25                         and

1                   “(II) a compounded drug product  
2                   intended for any use not described in  
3                   subclause (I).

4                   “(6) REGISTRATION.—

5                   “(A) ESTABLISHMENT OF PROCESS.—The  
6                   Secretary, in consultation with experts and rep-  
7                   resentatives of stakeholders including phar-  
8                   macies, compounding pharmacies, State regu-  
9                   lators, and health care providers, shall establish  
10                  a process for pharmacies described in sub-  
11                  section (a)(1)(A) to register as a compounding  
12                  pharmacy. Such registration shall be conducted  
13                  through an electronic method.

14                  “(B) REGISTRATION REQUIREMENT.—Ex-  
15                  cept as provided in subparagraph (C), in order  
16                  to be registered with the Secretary for purposes  
17                  of subsection (a)(1)(A), every person who owns  
18                  or operates a pharmacy shall submit to the Sec-  
19                  retary, in such time and manner as the Sec-  
20                  retary may require—

21                         “(i) contact information for the phar-  
22                         macy;

23                         “(ii) the State or States that the  
24                         pharmacy is licensed in;

1 “(iii) the methods used by the facility  
2 in compounding; and

3 “(iv) any additional information re-  
4 quired by the Secretary, which may include  
5 the quantity of product compounded at  
6 such pharmacy for the purpose of deter-  
7 mining if a drug manufacturing facility is  
8 inappropriately registering as a compound-  
9 ing pharmacy.

10 “(C) EXCEPTION.—A pharmacy shall be  
11 exempt from the requirement to register under  
12 subsection (a)(1)(A) if the pharmacy—

13 “(i) employs fewer than 20 full-time  
14 employees (or 20 full-time equivalents);  
15 and

16 “(ii) performs traditional compound-  
17 ing of drug products for use in a single  
18 State.”; and

19 (3) by adding at the end the following:

20 “(g) DATABASE.—

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

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

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

6           “(C) other information determined relevant  
7           by the Secretary.

8           “(2) DESIGN.—The database under paragraph  
9           (1)—

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

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

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

23           “(h) MINIMUM STANDARDS.—

1           “(1) The Secretary shall establish minimum  
2 standards for the safe production of compounded  
3 drug products.

4           “(2) The Secretary shall determine these min-  
5 imum standards and shall determine the drug prod-  
6 ucts that must meet the minimum standards.

7           “(3) The standards may include but is not lim-  
8 ited to the intended route of administration and if  
9 the drug is sterile or non-sterile. If appropriate, the  
10 Secretary may consider the different types of drug  
11 products and set appropriate minimum standards  
12 for specific drug types or drug uses.

13           “(i) TRAINING.—The Secretary shall conduct a series  
14 of regional training opportunities for State agencies that  
15 regulate pharmacies that compound drug products. These  
16 training opportunities should include information on the  
17 minimum standards discussed in (h), sample inspection  
18 protocol, and recordkeeping to facilitate the inclusion of  
19 State findings and inspections into the database discussed  
20 in (g).”.

21           (b) DEADLINES AND ADVISORY COMMITTEES.—

22           (1) DEADLINE FOR ISSUANCE OF REGULA-  
23 TIONS.—Not later than 18 months after the date of  
24 enactment of this Act, the Secretary of Health and

1 Human Services shall issue regulations to imple-  
2 ment—

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

6 (B) subsection (g) of section 503A of such  
7 Act.

8 (2) LABELING ADVISORY COMMITTEE.—

9 (A) ESTABLISHMENT.—The Secretary of  
10 Health and Human Services shall establish an  
11 advisory committee on labeling (as defined in  
12 section 201 of the Federal Food, Drug, and  
13 Cosmetic Act (21 U.S.C. 321)) of compounded  
14 drug products and shall consult such committee  
15 in the development of the regulations under  
16 paragraph (1)(A).

17 (B) MEMBERSHIP.—The advisory com-  
18 mittee shall include representatives of patients  
19 or consumers, health care providers, compound-  
20 ing pharmacies, State agencies that regulate  
21 compounding pharmacies, and at least one  
22 member with expertise on clearly commu-  
23 nicating information in such labeling of drugs.

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

4           (D) RECOMMENDATIONS.—Not later than  
5 12 months after the date of enactment of this  
6 Act, the advisory committee shall submit to the  
7 Secretary of Health and Human Services rec-  
8 ommendations on the regulations under para-  
9 graph (1)(A), including recommendations on  
10 the type of information and language that  
11 should be included on the labels of drug prod-  
12 ucts that are compounded pursuant to section  
13 503A of the Federal Food, Drug, and Cosmetic  
14 Act.

15           (E) TERMINATION.—The advisory com-  
16 mittee under this subparagraph shall terminate  
17 upon the submission of the recommendations  
18 under subparagraph (D).

19 (3) DATABASE ADVISORY COMMITTEE.—

20           (A) ESTABLISHMENT.—The Secretary of  
21 Health and Human Services shall establish an  
22 advisory committee on the database described  
23 in section 503A(g) of the Federal Food, Drug,  
24 and Cosmetic Act, as added by subsection (a),  
25 and shall consult such committee in the devel-

1           opment of the regulations under paragraph  
2           (1)(B).

3           (B) MEMBERSHIP.—The advisory com-  
4           mittee shall include representatives of patients  
5           or consumers, health care providers, compound-  
6           ing pharmacies, State agencies that regulate  
7           compounding pharmacies, and information tech-  
8           nology experts.

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

12          (D) RECOMMENDATIONS.—Not later than  
13          12 months after the date of enactment of this  
14          Act, the advisory committee shall submit to the  
15          Secretary of Health and Human Services rec-  
16          ommendations on the regulations under para-  
17          graph (1)(B).

18          (E) TERMINATION.—The advisory com-  
19          mittee under this subparagraph shall terminate  
20          upon the submission of the recommendations  
21          under subparagraph (D).

22          (4) PERMANENT ADVISORY COMMITTEE ON  
23          PHARMACY COMPOUNDING.—The Secretary shall  
24          convene the Advisory Committee on Pharmacy  
25          Compounding as appropriate to consider issues re-

1       lated to the safety and availability of compounded  
2       drug products.

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

4       (a) **BIANNUAL REPORTS.**—Not later than 6 months  
5 after the date of enactment of this Act, and at the end  
6 of each succeeding 6-month period that ends before the  
7 25th month after the date of enactment of this Act, the  
8 Secretary of Health and Human Services shall submit to  
9 the Congress a report on the status of the implementation  
10 of the requirements of this Act, and the amendments made  
11 by this Act.

12       (b) **THIRD-PARTY ACCREDITATION.**—Not later than  
13 12 months after the date of enactment of this Act, the  
14 Secretary shall submit to the Congress a report that con-  
15 tains—

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

19               (2) an evaluation of the effectiveness of such  
20 standards in ensuring the production of safe and ef-  
21 fective compounded drug products.

22       (c) **STRUCTURE OF STATE OVERSIGHT.**—Not later  
23 than 18 months after the date of enactment of this Act,  
24 the Secretary shall submit to the Congress a report that  
25 contains—

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

6           (2) consideration of how the structure and rela-  
7           tionship of State regulators may impact the develop-  
8           ment and enforcement of regulations to ensure safe  
9           compounded drug products.

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

12           (1) the extent to which Federal health care pro-  
13           grams (as such term is defined in section 1128B(f)  
14           of the Social Security Act (42 U.S.C. 1320a–7b))  
15           ensure that compounded drug products which are  
16           paid for by such programs are compounded in facili-  
17           ties that comply with the requirements of the Fed-  
18           eral Food, Drug, and Cosmetic Act (21 U.S.C. 301  
19           et seq.);

20           (2) whether the reimbursement rates for com-  
21           pounded drug products under such Federal health  
22           care programs are appropriate, taking into consider-  
23           ation the cost of production of such compounded  
24           drug products; and

1           (3) whether such Federal health care programs  
2           encourage the use of compounded drug products in  
3           place of otherwise available lawfully marketed drug  
4           products.

5 **SEC. 4. PROHIBITIONS AND PENALTIES.**

6           (a) PROHIBITION OF VIOLATIONS OF SECTION  
7 503A.—Section 301(d) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 331(d)) is amended by inserting  
9 “503A,” before “505,”.

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

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

16                   “(A) knowingly and intentionally to de-  
17                   fraud or mislead; or

18                   “(B) with conscious or reckless disregard  
19                   of a risk of death or serious bodily injury,  
20           shall be fined under title 18, United States Code,  
21           imprisoned for not more than 10 years, or both.”.

○