

112TH CONGRESS
2D SESSION

H. R. 6584

To amend the Federal Food, Drug, and Cosmetic Act to provide for the compounding of drug products.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 2, 2012

Mr. MARKEY (for himself, Mr. COHEN, Ms. SLAUGHTER, Mr. LYNCH, and Mr. OLVER) 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 provide for the compounding of 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 “Verifying Authority
5 and Legality In Drug Compounding Act of 2012”.

6 **SEC. 2. APPLICATION OF FEDERAL LAW TO PRACTICE OF**
7 **PHARMACY COMPOUNDING.**

8 (a) AMENDMENT.—Section 503A of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is
10 amended to read as follows:

1 **“SEC. 503A. PHARMACY COMPOUNDING.**

2 “(a) IN GENERAL.—Sections 501(a)(2)(B) and 505
3 shall not apply with respect to a drug product if each of
4 the following applies:

5 “(1) The drug product is compounded for an
6 identified individual patient based on the receipt
7 of—

8 “(A) a valid prescription order; or

9 “(B) a notation, approved by the pre-
10 scribing practitioner, on the prescription order
11 that a compounded product is necessary for the
12 identified patient.

13 “(2) The drug product is compounded by a li-
14 censed pharmacist in a State-licensed pharmacy or a
15 Federal facility, or by a licensed physician, pursuant
16 to such prescription order or notation.

17 “(3) The drug product is compounded exclu-
18 sively from—

19 “(A) ingredients that comply with the
20 standards of an applicable United States Phar-
21 macopoeia or National Formulary monograph;
22 or

23 “(B) if such a monograph does not exist,
24 ingredients that are ingredients in a drug—

1 “(i) for which an approval of an appli-
2 cation filed under subsection (b) or (j) of
3 section 505 is in effect; or

4 “(ii) that may be lawfully marketed in
5 the United States without such an ap-
6 proval pursuant to the definition of a new
7 drug in section 201.

8 “(4) Any bulk substance used for purposes of
9 compounding the drug product—

10 “(A) is manufactured by an establishment
11 that is registered under section 510 (including
12 a foreign establishment that is registered under
13 section 510(i)); and

14 “(B) is accompanied by valid certificates of
15 analysis.

16 “(5) The pharmacist or physician compounding
17 the drug product complies with the standards of any
18 applicable United States Pharmacopoeia chapters on
19 pharmacy compounding.

20 “(6) The drug product, including the dosage
21 form and any ingredient thereof, is not included in
22 the list under subsection (b).

23 “(7) The drug product is not a copy of a com-
24 mercially available drug.

1 “(b) LIST OF DRUG PRODUCTS THAT SHOULD NOT
2 BE COMPOUNDED.—

3 “(1) IN GENERAL.—For purposes of subsection
4 (a)(6), the Secretary shall—

5 “(A) develop and maintain a list of drug
6 products that should not be compounded, in-
7 cluding any categories, dosage forms, or ingre-
8 dients of such drug products; and

9 “(B) include on such list, at a minimum—

10 “(i) drug products (or categories, dos-
11 age forms, or ingredients thereof) whose
12 compounding is reasonably likely to cause
13 an adverse effect on safety or effectiveness
14 of such drug product; and

15 “(ii) drug products (or categories,
16 dosage forms, or ingredients thereof) that
17 have been withdrawn or removed from the
18 market because they have been found to be
19 unsafe or not effective.

20 “(2) INITIAL PUBLICATION; UPDATES.—The
21 Secretary shall—

22 “(A) not later than 1 year after the date
23 of the enactment of the Verifying Authority and
24 Legality In Drug Compounding Act of 2012,
25 publish an initial list under paragraph (1); and

1 “(B) not less frequently than every year
2 thereafter, review and, as appropriate, update
3 the list under paragraph (1).

4 “(3) AVAILABILITY.—The Secretary shall make
5 the list under paragraph (1) available on the public
6 Web site of the Food and Drug Administration.

7 “(4) TRANSMISSION TO STATE REGULATORY
8 AGENCIES.—Upon publication of the initial list
9 under paragraph (1), and upon each update to the
10 list, the Secretary shall transmit an up-to-date copy
11 of the list to the agency in each State with primary
12 responsibility for regulating the compounding of
13 drugs.

14 “(c) WAIVER OF REQUIREMENT OF INDIVIDUALLY
15 IDENTIFIED PATIENT FOR SPECIFIED DRUG PROD-
16 UCTS.—

17 “(1) WAIVER AUTHORITY.—The Secretary may,
18 with respect to a drug product sold or dispensed by
19 a pharmacy or pharmacist, waive the requirement of
20 subsection (a)(1) that the drug product be com-
21 pounded for an individually identified patient if the
22 Secretary determines that compounding the drug
23 product is necessary—

24 “(A) to address a drug shortage; or

25 “(B) to protect public health or well-being.

1 “(2) DURATION.—The duration of a waiver
2 under paragraph (1) shall not exceed 1 year, unless
3 the Secretary determines that an extension is nec-
4 essary to continue—

5 “(A) to address the drug shortage for
6 which such waiver was originally approved; or

7 “(B) to protect public health or well-being.

8 “(3) WAIVERS BY STATES PROHIBITED.—The
9 Secretary may not authorize any State to grant
10 waivers under this subsection.

11 “(d) WAIVER OF REQUIREMENT OF INDIVIDUALLY
12 IDENTIFIED PATIENT FOR SPECIFIED PHARMACIES AND
13 PHARMACISTS.—

14 “(1) WAIVER AUTHORITY.—The Secretary may
15 waive the requirement of subsection (a)(1) that the
16 drug product be compounded for an individually
17 identified patient if the pharmacy or pharmacist—

18 “(A) submits an application that meets the
19 requirements of paragraph (5)(A) and is satis-
20 factory to the Secretary (or, subject to para-
21 graph (3), the State); and

22 “(B) agrees to comply with any condition
23 of operation and any limitations specified by the
24 Secretary as a requirement for such waiver, in-

1 including the conditions and limitations specified
2 under paragraph (5).

3 “(2) INELIGIBLE PHARMACIES.—A pharmacy or
4 pharmacist required to be registered under section
5 510 for purposes of compounding a drug product is
6 not eligible for a waiver under this subsection for
7 such purposes.

8 “(3) TYPES OF PHARMACIES ELIGIBLE FOR
9 WAIVER.—Subject to paragraph (2), the Secretary
10 shall specify types of pharmacies and pharmacists
11 that are eligible for a waiver under this subsection,
12 and shall include the following types:

13 “(A) Any pharmacy or pharmacist within a
14 hospital system that is compounding drug prod-
15 ucts exclusively for dispensing to patients with-
16 in that hospital system.

17 “(B) Any pharmacy or pharmacist that
18 compounds sterile drug products.

19 “(C) Any pharmacy or pharmacist that
20 compounds drug products in limited quantities
21 before the receipt of a valid prescription for an
22 individual patient who is located in the same
23 State as the pharmacy or pharmacist, based on
24 a history of the pharmacy or pharmacist receiv-
25 ing such valid prescription.

1 “(4) WAIVERS BY STATES ALLOWED.—

2 “(A) MEMORANDUM OF UNDER-
3 STANDING.—The Secretary may authorize a
4 State to grant waivers under paragraph (1) to
5 pharmacies and pharmacists in such State pur-
6 suant to a memorandum of understanding en-
7 tered into between the Secretary and the
8 State—

9 “(i) ensuring, to the Secretary’s satis-
10 faction, that the State’s program for
11 granting waivers will be implemented in
12 accordance with the requirements of this
13 section (including the application of dif-
14 ferent requirements for different types of
15 pharmacies, as specified under paragraph
16 (5)(B)); and

17 “(ii) including such other information
18 and assurances as the Secretary may re-
19 quire.

20 “(B) DETERMINATION.—The Secretary
21 shall establish criteria and a process for deter-
22 mining whether to authorize a State to grant
23 waivers under paragraph (1).

24 “(C) SCOPE OF AUTHORIZATION.—In au-
25 thorizing a State to grant waivers under sub-

1 paragraph (A), the Secretary may limit such
2 authority to apply only with respect to certain
3 types of pharmacies and pharmacists specified
4 under paragraph (3).

5 “(D) LIMITATION.—A waiver granted by a
6 State to a pharmacy or pharmacist under sub-
7 paragraph (A) shall only apply with respect to
8 compounded drug products sold or dispensed
9 within such State.

10 “(5) APPLICATIONS; REQUIREMENTS.—

11 “(A) IN GENERAL.—For each type of
12 pharmacy or pharmacist specified under para-
13 graph (3), the Secretary shall specify, in the
14 regulations under subsection (j), the following:

15 “(i) The information that is required
16 to be included in an application for a waiv-
17 er under paragraph (1).

18 “(ii) The circumstances necessary to
19 support the approval of such an applica-
20 tion by the Secretary, or by a State that
21 is authorized to grant waivers under para-
22 graph (4), including the criteria that shall
23 be used to evaluate such an application.

24 “(iii) The conditions of operation, in-
25 cluding good manufacturing practices and

1 requirements for third-party testing, appli-
2 cable to the compounding of drugs under
3 such a waiver.

4 “(iv) Any limitations on the activities
5 that a pharmacy or pharmacist may en-
6 gage in under such a waiver.

7 “(v) The duration (and renewability)
8 of such a waiver.

9 “(B) SPECIFICITY TO TYPES OF PHAR-
10 MACIES AND PHARMACISTS.—In establishing re-
11 quirements under subparagraph (A), the Sec-
12 retary shall make the requirements specific to
13 each type of pharmacy and pharmacist specified
14 by the Secretary under paragraph (3).

15 “(e) WAIVER OF REQUIREMENT REGARDING COPIES
16 OF COMMERCIALLY AVAILABLE DRUG.—

17 “(1) WAIVER AUTHORITY.—The Secretary may,
18 with respect to a drug product sold or dispensed by
19 a pharmacy or pharmacist, waive the requirement of
20 subsection (a)(7) if the Secretary determines that
21 compounding the drug product is necessary to pro-
22 tect public health or well-being.

23 “(2) DURATION.—The duration of a waiver
24 under paragraph (1) shall not exceed 1 year, unless

1 the Secretary determines that an extension is nec-
2 essary to protect public health or well-being.

3 “(3) WAIVERS BY STATES PROHIBITED.—The
4 Secretary may not authorize any State to grant
5 waivers under this subsection.

6 “(f) INSPECTIONS.—The facilities of any pharmacy
7 or pharmacist compounding drug products pursuant to a
8 waiver under subsection (c), (d), or (e) shall be subject
9 to inspection under section 704 for purposes of deter-
10 mining compliance with the provisions of this Act applica-
11 ble to such compounding.

12 “(g) CANCELLATION OF WAIVER.—

13 “(1) IN GENERAL.—The Secretary shall publish
14 notice at least 30 days before cancelling a waiver
15 under subsection (c), (d), or (e).

16 “(2) EXCEPTION FOR PUBLIC HEALTH AND
17 SAFETY.—The Secretary may cancel a waiver with-
18 out regard to paragraph (1) in order to prevent an
19 adverse impact on public health or safety.

20 “(h) LABELING.—The labeling of any drug product
21 compounded pursuant to subsection (a) shall include the
22 following statement: ‘This drug has not been tested for
23 safety and effectiveness and is not approved by the FDA.
24 Serious adverse reactions to this drug should be reported
25 to the pharmacy where it was received and the FDA at

1 _____.’ The blank shall specify a phone number and
2 a Web site, to be provided by the Secretary for purposes
3 of this subsection.

4 “(i) REPORTING BY PHARMACISTS AND PHYSI-
5 CIANS.—

6 “(1) ADVERSE EVENT.—If a pharmacist or
7 physician compounding a drug product pursuant to
8 this section becomes aware of any adverse event as-
9 sociated with the use of such product, not later than
10 10 calendar days after becoming so aware, the phar-
11 macist or physician shall report such adverse event
12 to the Secretary.

13 “(2) INFORMATION RELATED TO RISK OF IN-
14 JURY OR DEATH.—If a pharmacist or physician
15 compounding a drug product pursuant to this sec-
16 tion becomes aware of information concerning any
17 bacteriological, fungal, or other contamination; any
18 significant chemical, physical, or other change; or
19 any deterioration of a compounded drug product
20 that has already been distributed by the pharmacist
21 or physician, that could cause serious injury or
22 death, not later than 5 calendar days after becoming
23 so aware, the pharmacist or physician shall report
24 such information to the Secretary.

1 “(j) REGULATIONS.—The Secretary shall promulgate
2 regulations for carrying out this section, which shall in-
3 clude the following:

4 “(1) The types of pharmacies and pharmacists
5 specified pursuant to subsection (d)(3).

6 “(2) The criteria and process for determining
7 whether a State may provide a waiver under sub-
8 section (d)(4).

9 “(3) The information specified under subsection
10 (d)(5)(A).

11 “(4) The requirements applicable to different
12 types of pharmacies and pharmacists under sub-
13 section (d)(5).

14 “(5) The requirements for inspections under
15 subsection (f).

16 “(k) DEFINITIONS.—In this section:

17 “(1) The term ‘copy of a commercially available
18 drug product’ does not include a drug product in
19 which there is a change, made for an identified indi-
20 vidual patient, which produces for that patient a sig-
21 nificant difference, as determined by the prescribing
22 practitioner, between the compounded drug and the
23 comparable commercially available drug product.

24 “(2) The term ‘compounding’ does not include
25 mixing, reconstituting, or other such acts that are

1 performed in accordance with directions contained in
2 approved labeling provided by the product’s manu-
3 facturer and other manufacturer directions con-
4 sistent with that labeling.”.

5 (b) MISBRANDING.—Section 502 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
7 ed by adding at the end the following:

8 “(bb) If it is a drug product compounded pursuant
9 to section 503A and its labeling does not include the state-
10 ment required by section 503A(h).”.

11 (c) CONFORMING AMENDMENT.—Section
12 704(a)(2)(A) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 374(a)(2)(A)) is amended by inserting
14 “subject to section 503A,” before “pharmacies which
15 maintain establishments”.

16 (d) REGULATIONS.—Not later than 1 year after the
17 date of the enactment of this Act, the Secretary shall pro-
18 mulgate final regulations for carrying out the amendments
19 made by subsections (a), (b), and (c).

20 (e) EFFECTIVE DATE.—The amendments made by
21 subsections (a), (b), and (c) shall take effect on the date
22 that is 1 year after the date of the enactment of this Act.

1 **SEC. 3. REGISTRATION AND INSPECTION OF MANUFACTUR-**
2 **ERS COMPOUNDING DRUG PRODUCTS.**

3 (a) REGISTRATION.—Section 510(g) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360(g)) is
5 amended by adding at the end the following: “With respect
6 to compounding drugs, the exemption in paragraph (1)
7 does not apply with respect to any pharmacy to the extent
8 to which the pharmacy is, in effect, manufacturing such
9 drugs, as determined by the Secretary, taking into consid-
10 eration the extent to which such pharmacy sells the drugs
11 across State lines, the quantity of the drugs sold, and any
12 other factors determined appropriate by the Secretary.”.

13 (b) INSPECTION.—Section 704(a)(2) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(2)) is
15 amended by adding at the end the following flush text:

16 “With respect to compounding drugs, the exemption
17 in subparagraph (A) does not apply with respect to
18 any pharmacy to the extent to which the pharmacy
19 is, in effect, manufacturing such drugs, as deter-
20 mined by the Secretary, taking into consideration
21 the extent to which such pharmacy sells the drugs
22 across State lines, the quantity of the drugs sold,
23 and any other factors determined appropriate by the
24 Secretary.”.

25 (c) REGULATIONS.—Not later than 1 year after the
26 date of the enactment of this Act, the Secretary of Health

1 and Human Services shall promulgate regulations for car-
2 rying out the amendments made by subsections (a) and
3 (b).

4 (d) EFFECTIVE DATE.—The amendment made by
5 subsection (a) shall take effect on the date that is 1 year
6 after the date of the enactment of this Act.

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