

110TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians.

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IN THE SENATE OF THE UNITED STATES

\_\_\_\_\_ introduced the following bill; which was read twice  
and referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians.

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 “Safe Drug  
5 Compounding Act of 2007”.

6 **SEC. 2. PHARMACY COMPOUNDING.**

7 Section 503A of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 353a) is amended to read as follows:

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

2 “(a) DEFINITIONS.—In this section—

3 “(1) the term ‘bulk drug substance’ has the  
4 meaning given the term in section 207.3(a)(4) of  
5 title 21, Code of Federal Regulations (or any suc-  
6 cessor regulation);

7 “(2) the term ‘compounding’—

8 “(A) includes the process by which a phar-  
9 macist or doctor combines, mixes, or alters in-  
10 gredients to create a drug tailored to the needs  
11 of an individual patient; and

12 “(B) does not include mixing, reconsti-  
13 tuting, or other such acts that are performed in  
14 accordance with directions contained in ap-  
15 proved labeling provided by a product’s manu-  
16 facturer and other manufacturer directions con-  
17 sistent with that labeling;

18 “(3) the term ‘essentially a copy of a drug ap-  
19 proved by the Secretary’—

20 “(A) includes a drug product for which  
21 there is no legitimate medical need for any dif-  
22 ference in ingredients, dosage form, route of ad-  
23 ministration, or strength from the comparable  
24 drug approved by the Secretary; and

25 “(B) does not include a drug product in  
26 which there is a change, made for an identified

1 individual patient, which produces for that pa-  
2 tient a significant difference, as determined by  
3 the prescribing practitioner, between the com-  
4 pounded drug and the comparable drug ap-  
5 proved by the Secretary;

6 “(4) the term ‘sterile drug product’ means any  
7 drug product—

8 “(A) to be administered parenterally;

9 “(B) for topical use on or in the eye;

10 “(C) that is an aqueous-based solution for  
11 inhalation; or

12 “(D) that the Secretary defines by regula-  
13 tion to be a sterile drug product; and

14 “(5) the term ‘valid prescription order’ means  
15 a prescription order—

16 “(A) for an identified patient; and

17 “(B) completed by a practitioner author-  
18 ized by State law to prescribe drugs that is  
19 within an established relationship with such pa-  
20 tient.

21 “(b) APPLICATION.—

22 “(1) APPLICABILITY OF ACT TO COMPOUNDED  
23 DRUG PRODUCTS.—

1           “(A) IN GENERAL.—Except as provided in  
2           subparagraph (B), this Act shall apply to com-  
3           pounded drug products.

4           “(B) EXEMPTION FOR CERTAIN DRUGS.—  
5           Sections 501(a)(2)(B), 502(f)(1), and 505 shall  
6           not apply to a compounded drug product if,  
7           with respect to such compounded drug product,  
8           the requirements of this section are met.

9           “(C) NO EXEMPTION FOR NON-COMPLIANT  
10          DRUGS.—Sections 501(a)(2)(B), 502(f)(1), and  
11          505 shall apply to a compounded drug product  
12          if, with respect to such compounded drug prod-  
13          uct, the requirements of this section are not  
14          met.

15          “(2) APPLICATION OF SECTION.—This section  
16          shall not apply to—

17                 “(A) compounded positron emission tomog-  
18                 raphy drugs, as defined in section 201(ii); or

19                 “(B) radiopharmaceuticals.

20          “(c) COMPOUNDING.—

21                 “(1) IN GENERAL.—Drug products that are  
22                 compounded shall be compounded only in accordance  
23                 with this paragraph as follows:



1           scribing practitioner, on a valid  
2           prescription order that the pre-  
3           scribing practitioner has deter-  
4           mined that a compounded drug  
5           product is needed by the identi-  
6           fied individual patient, subject to  
7           clause (ii); or

8           “(II) in limited quantities before  
9           the receipt of such valid prescription  
10          orders for such individual patients  
11          when based on a history of the  
12          compounding pharmacist or physician  
13          receiving such valid prescription or-  
14          ders for the compounding of the drug  
15          product, which orders have been gen-  
16          erated solely within an established re-  
17          lationship between—

18                 “(aa) the compounding  
19                 pharmacist or physician; and

20                 “(bb)(AA) such individual  
21                 patients for whom such prescrip-  
22                 tion orders will be provided; or

23                 “(BB) the practitioners who  
24                 will write such prescription or-  
25                 ders.

1                   “(ii) NOTATION.—A compounding  
2 pharmacist or physician may make a nota-  
3 tion as described in clause (i)(I)(bb), if the  
4 drug approved by the Secretary that the  
5 valid prescription order indicates should be  
6 dispensed to the individual patient is not  
7 immediately available for dispensing to the  
8 patient, either because the drug is not  
9 stocked or is in short supply, in which case  
10 the compounding pharmacist or physician  
11 may dispense a quantity of a compounded  
12 drug product only in a quantity necessary  
13 to ensure the health and safety of the pa-  
14 tient through the time reasonably expected  
15 to be required to acquire the drug ap-  
16 proved by the Secretary.

17                   “(C) DISPENSING BY COMPOUNDING PHAR-  
18 MACIST OR PHYSICIAN.—A compounded drug  
19 product shall be dispensed to the individual pa-  
20 tient for which the drug product was pre-  
21 scribed—

22                   “(i) on receipt of the valid prescrip-  
23 tion order described in subparagraph  
24 (B)(i)(I); and

1                   “(ii) by the compounding pharmacist  
2                   or physician, unless the patient is an inpa-  
3                   tient at a health care facility, such as a  
4                   hospital.

5                   “(D) BULK DRUG SUBSTANCES.—A drug  
6                   product shall be compounded using bulk drug  
7                   substances that—

8                   “(i)(I) are drug substances that are  
9                   components of drugs approved by the Sec-  
10                  retary;

11                  “(II) if the drug substance is not a  
12                  component of a drug approved by the Sec-  
13                  retary, comply with the standards of an  
14                  applicable United States Pharmacopoeia or  
15                  National Formulary monograph, if a  
16                  monograph exists, and the United States  
17                  Pharmacopoeia chapter on pharmacy  
18                  compounding; or

19                  “(III) if the drug substance is not a  
20                  component of a drug approved by the Sec-  
21                  retary and such a monograph does not  
22                  exist, appear on a list developed by the  
23                  Secretary through regulations issued by  
24                  the Secretary under subsection (e);

1           “(ii) are manufactured by an estab-  
2           lishment that is registered under section  
3           510 (including a foreign establishment that  
4           is registered under section 510(i)); and

5           “(iii) are accompanied by valid certifi-  
6           cates of analysis for each bulk drug sub-  
7           stance (which certificates shall be main-  
8           tained for a period of not less than 2 years  
9           after the drug product is dispensed or the  
10          drug substance is disposed of, whichever is  
11          later).

12          “(E) OTHER INGREDIENTS.—Ingredients  
13          (other than bulk drug substances) that are used  
14          in the compounding of a drug product shall—

15               “(i) comply with the standards of an  
16               applicable United States Pharmacopoeia or  
17               National Formulary monograph, if a  
18               monograph exists;

19               “(ii) comply with the standards of the  
20               United States Pharmacopoeia chapter on  
21               pharmacy compounding; and

22               “(iii)(I) be listed in the Inactive In-  
23               redient Guide of the Food and Drug Ad-  
24               ministration as approved in a product with

1 the same route of administration and with-  
2 in the potency range listed; and

3 “(II) not be identified as inappro-  
4 priate for such a drug product on the list  
5 published by the Secretary in the Federal  
6 Register as provided for in subsection  
7 (e)(3).

8 “(F) STERILE DRUG PRODUCTS.—A sterile  
9 drug product shall be compounded—

10 “(i) solely from ingredients that are—

11 “(I) sterile; and

12 “(II) tested and determined by  
13 the compounding pharmacist or physi-  
14 cian to be free of endotoxins or other  
15 filth that may make the drug product  
16 injurious to health; and

17 “(ii) in conformity with—

18 “(I) standards for sterile  
19 compounding established by the Sec-  
20 retary by regulation; or

21 “(II) if such regulations do not  
22 exist, standards of the United States  
23 Pharmacopoeia for sterile  
24 compounding.

1                   “(G) REQUIRED DISCLOSURES IN LABEL-  
2                   ING.—

3                   “(i) IN GENERAL.—A compounded  
4                   drug product shall be dispensed with label-  
5                   ing containing—

6                   “(I) the statement ‘This drug  
7                   was made specifically for you, because  
8                   your health care provider determined  
9                   that no FDA-approved product would  
10                  suit your needs. It must comply with  
11                  Federal and State pharmacy guide-  
12                  lines for preparing drugs, but is not  
13                  required to meet the safety, efficacy,  
14                  or manufacturing standards for FDA-  
15                  approved drugs. If you have questions  
16                  about this medication, ask your health  
17                  care provider.’;

18                  “(II) if the drug product is a  
19                  sterile drug product, the additional  
20                  statement ‘This drug was not pre-  
21                  pared using FDA’s manufacturing  
22                  standards for sterile drugs’;

23                  “(III) the date on which the drug  
24                  was compounded;

1                   “(IV) the name of the licensed  
2                   compounding pharmacist or  
3                   compounding physician; and

4                   “(V) relevant information from  
5                   labeling, including from medication  
6                   guides, required by the Secretary to  
7                   be provided to patients when a drug  
8                   approved by the Secretary with an ac-  
9                   tive ingredient used in the com-  
10                  pounded drug product is dispensed to  
11                  patients.

12                  “(ii)       NONAPPLICATION.—Clause  
13                  (i)(II) shall not apply to the labeling of a  
14                  sterile drug product if the facility in which  
15                  the sterile drug product is compounded  
16                  is—

17                       “(I) registered under section 510;  
18                       and

19                       “(II) found by the Secretary,  
20                       after an inspection under section 704,  
21                       to be in compliance with the require-  
22                       ments of section 501(a)(2)(B) for  
23                       manufacturing sterile drug products.

24                       “(H) REQUIRED DISCLOSURES IN ADVER-  
25                       TISING.—

1           “(i) REQUIRED STATEMENT FOR DI-  
2           RECT-TO-CONSUMER ADVERTISING OF A  
3           COMPOUNDED DRUG.—Any advertising or  
4           promotion directed to consumers of a com-  
5           pounded drug, shall include the following  
6           statement that is displayed or stated  
7           prominently and conspicuously: ‘This drug  
8           can be made specifically for you by a phar-  
9           macist if your health care provider deter-  
10          mines that no FDA-approved product  
11          would suit your needs. It must comply with  
12          Federal and State pharmacy guidelines for  
13          preparing drugs, but is not required to  
14          meet safety and efficacy standards for  
15          FDA-approved drugs. If you have ques-  
16          tions about this medication, ask your  
17          health care provider.’.

18           “(ii) REQUIRED STATEMENT FOR AD-  
19          VERTISING OF A COMPOUNDED DRUG TO  
20          HEALTH CARE PROVIDERS.—Any adver-  
21          tising or promotion directed to health care  
22          providers of a compounded drug shall in-  
23          clude the following statement that is dis-  
24          played or stated prominently and conspicu-  
25          ously: ‘This drug can be made specifically

1 for your patient by a pharmacist if you de-  
2 cide that no FDA-approved product would  
3 suit that patient's needs. Such com-  
4 pounded drugs must comply with Federal  
5 and State pharmacy guidelines but are not  
6 required to meet the safety and efficacy  
7 standards for FDA-approved drugs.'.

8 “(iii) REQUIRED STATEMENT FOR AD-  
9 VERTISING OF COMPOUNDING SERVICES.—

10 Any advertising or promotion of more than  
11 1 compounded drug or of compounding  
12 services by a pharmacist or physician, shall  
13 include the following statement that is dis-  
14 played or stated prominently and conspicu-  
15 ously: ‘Compounded drugs can be made  
16 specifically for a patient when the patient’s  
17 health care provider determines that no  
18 FDA-approved product meets the patient’s  
19 needs. Such compounded drugs must com-  
20 ply with Federal and State pharmacy  
21 guidelines for preparing drugs, but are not  
22 required to meet safety and efficacy stand-  
23 ards for FDA-approved drugs. Patients  
24 with questions about such medications  
25 should ask their health care providers.’.



1                   ments of section 501(a)(2)(B) for  
2                   manufacturing sterile drug products.

3                   “(2) DRUG PRODUCTS THAT SHALL NOT BE  
4                   COMPOUNDED.—A drug product shall not be com-  
5                   pounded if the drug product is—

6                   “(A) essentially a copy of a drug approved  
7                   by the Secretary, except in a quantity necessary  
8                   to ensure the health and safety of a patient  
9                   through the time reasonably expected to be re-  
10                  quired to acquire the drug approved by the Sec-  
11                  retary;

12                  “(B) a drug that appears on the list pub-  
13                  lished by the Secretary in the Federal Register,  
14                  and published in section 216.24 of title 21,  
15                  Code of Federal Regulations (or any successor  
16                  regulation), of drug products that have been  
17                  withdrawn or removed from the market because  
18                  such drug products or components of such drug  
19                  products have been found to be unsafe or not  
20                  effective; or

21                  “(C) identified by the Secretary by regula-  
22                  tion as a drug product that presents demon-  
23                  strable difficulties for compounding that reason-  
24                  ably demonstrate an adverse effect on the safe-  
25                  ty or effectiveness of that drug product.

1           “(d) SEMI-ANNUAL REPORTS FOR DRUGS DISTRIB-  
2   UTED OUTSIDE STATE IN WHICH COMPOUNDED.—

3           “(1) IN GENERAL.—A pharmacist or physician  
4   who compounds drugs shall submit to the Secretary  
5   a semi-annual report providing, for each distinct  
6   compounded drug product distributed by the phar-  
7   macist or physician outside the State in which such  
8   pharmacist or physician compounded the drug prod-  
9   uct—

10           “(A) the name of the drug product as or-  
11   dered on a prescription;

12           “(B) the generic names of all ingredients,  
13   and the chemical names of all ingredients with-  
14   out generic names included in the drug product;

15           “(C) the number of doses of the drug  
16   product distributed by such pharmacist or phy-  
17   sician outside such State;

18           “(D) the States to which the drug product  
19   was distributed;

20           “(E) the number of doses of the drug  
21   product distributed by such pharmacist or phy-  
22   sician within the State in which such phar-  
23   macist or physician compounded the drug prod-  
24   uct; and

1           “(F) all known serious adverse events as-  
2           sociated with use of the drug product.

3           “(2) STATE BOARDS OF PHARMACY AND MEDI-  
4           CINE.—The Secretary shall share the reports de-  
5           scribed under paragraph (1) with State boards of  
6           pharmacy and medicine, as appropriate, and work  
7           with such boards to—

8           “(A) discourage the distribution of inordi-  
9           nate amounts of compounded drug products in  
10          interstate commerce; and

11          “(B) encourage appropriate State inves-  
12          tigation of complaints relating to compounded  
13          drug products distributed outside such State.

14          “(e) REGULATIONS AND IMPLEMENTATION.—

15          “(1) IN GENERAL.—The Secretary shall issue  
16          regulations to implement subsections  
17          (c)(1)(D)(i)(III), (c)(2)(B), and (c)(2)(C). Before  
18          issuing regulations to implement such subsections,  
19          the Secretary shall convene and consult an advisory  
20          committee on compounding. The advisory committee  
21          shall include representatives from the National Asso-  
22          ciation of Boards of Pharmacy, the United States  
23          Pharmacopoeia, pharmacy, physician, consumer or-  
24          ganizations, and other experts selected by the Sec-  
25          retary.

1           “(2) LIMITING COMPOUNDING.—The Secretary,  
2           in consultation with the United States Pharma-  
3           copoeia Convention, Incorporated, shall promulgate  
4           regulations identifying drug substances that may be  
5           used in compounding under subsection  
6           (c)(1)(D)(i)(III) for which a monograph does not  
7           exist or which are not components of drug products  
8           approved by the Secretary. The Secretary shall in-  
9           clude in the regulation the criteria for such sub-  
10          stances, which shall include historical use, reports in  
11          peer reviewed medical literature, or other criteria the  
12          Secretary may identify.

13          “(3) COMPOUNDING RESTRICTION LIST.—The  
14          Secretary, after providing for not less than 6 months  
15          of public review and comment, shall publish in the  
16          Federal Register a list of active and inactive ingredi-  
17          ents and uses of ingredients that may compromise  
18          the safety or efficacy of a compounded drug product,  
19          including allergens or other substances that must be  
20          absent from some or all compounded drug products,  
21          chemicals that should not be used in some or all  
22          compounding processes, ingredients that should not  
23          be combined, or maximum levels of individual ingre-  
24          dients in a compounded drug product. The Secretary

1 shall update the list not less often than once every  
2 2 years.

3 “(4) GUIDANCE ON MEDICAL NEED.—The Sec-  
4 retary, in consultation with physicians, other health  
5 care providers licensed to prescribe drugs, and  
6 compounding pharmacists, shall develop and issue a  
7 guidance document that identifies—

8 “(A) the types of medical needs that jus-  
9 tify the use of a compounded drug, such as—

10 “(i) the need for a drug without a  
11 specified inactive ingredient or without an  
12 inactive ingredient from a specified source  
13 (such as milk or soy) because the patient  
14 is allergic to such ingredient or ingredients  
15 from such source and the drug approved  
16 by the Secretary contains such an ingre-  
17 dient;

18 “(ii) the need for a drug in a dosage  
19 form, route of administration, or strength  
20 that differs from drugs approved by the  
21 Secretary; and

22 “(iii) the need for a drug when there  
23 is a shortage of the drug approved by the  
24 Secretary; and

1           “(B) the means by which a licensed pre-  
2           scribing physician or other health care provider  
3           can notate such a medical need on a prescrip-  
4           tion form.

5           “(5) INORDINATE AMOUNTS.—The Secretary  
6           may issue a guidance document to describe the term  
7           ‘inordinate amounts of compounded drug products  
8           in interstate commerce’.

9           “(6) ELECTRONIC PRESCRIBING.—When devel-  
10          oping technical standards for electronic prescribing  
11          systems, the Secretary shall develop a standard so  
12          that a system certified by the Secretary shall allow  
13          a licensed prescribing physician or other health care  
14          provider to—

15                 “(A) prescribe a compounded drug;

16                 “(B) indicate the nature of the medical  
17                 need that requires the use of a compounded  
18                 drug rather than a drug approved by the Sec-  
19                 retary; and

20                 “(C) indicate that the prescribing provider  
21                 has discussed the risks and benefits of using  
22                 the compounded drug with the patient.

23          “(7) MEDICAL NEED EXCEPTION.—

24                 “(A) IN GENERAL.—The Secretary shall by  
25                 regulation identify circumstances in which med-

1           ical need justifies an exception from compliance  
2           with 1 or more requirements of this section,  
3           such as when a bulk drug substance that meets  
4           the requirements of subsection (c)(1)(D) or an  
5           ingredient other than bulk drug substance that  
6           meets the requirements of subsection (c)(1)(E)  
7           is not available to compound a drug product.

8           “(B) NOTIFICATION AND CONFIRMA-  
9           TION.—A regulation promulgated pursuant to  
10          subparagraph (A) shall require that, to use an  
11          exception—

12                 “(i) the compounding pharmacist or  
13                 physician notify the prescribing practi-  
14                 tioner who completed the valid prescription  
15                 order indicating that a compounded drug  
16                 product is needed by the identified patient,  
17                 of the nature of the exception to be used;

18                 “(ii) the prescribing physician confirm  
19                 the need for the compounded drug product  
20                 even given the nature of the exception to  
21                 be used;

22                 “(iii) the compounding pharmacist or  
23                 physician make a notation of such con-  
24                 firmation on such prescription order; and

1                   “(iv) such patient be informed, both  
2                   orally when the drug is dispensed or ad-  
3                   ministered and in the drug label, that the  
4                   compounded drug product was not com-  
5                   pounded in compliance with the normal  
6                   standards for compounding drugs.”.

7 **SEC. 3. CONFORMING AMENDMENTS.**

8           (a) INSPECTION.—Section 704(a) of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is  
10 amended by adding at the end the following:

11                   “(4) Notwithstanding any other provision of  
12                   this subsection, the provisions of the third sentence  
13                   of paragraph (1) shall apply to a retail pharmacy  
14                   that compounds drug products or dispenses com-  
15                   pounded drug products, to ensure compliance with  
16                   section 503A.”.

17           (b) ADVERTISEMENTS.—Section 502(n) of the Fed-  
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 352(n))  
19 is amended by striking “or distributor” each place it ap-  
20 pears and inserting “distributor, or compounder”.

21           (c) MODIFICATION OF MEDWATCH FORMS.—Not  
22 later than 6 months after the date of enactment of this  
23 Act, the Secretary of Health and Human Services shall  
24 modify the Medwatch mandatory and voluntary forms,  
25 and other drug safety surveillance systems, to facilitate

1 the gathering of information on, and correct attribution  
2 of, adverse events associated with the use of compounded  
3 drug products.

4 (d) AUTHORIZATION OF APPROPRIATIONS.—There  
5 are authorized to be appropriated to carry out this section  
6 such sums as may be necessary for each of the fiscal years  
7 2008 through 2012.