

112TH CONGRESS
2D SESSION

S. _____

To promote public notification and provide incentives to reduce drug shortages.

IN THE SENATE OF THE UNITED STATES

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

A BILL

To promote public notification and provide incentives to
reduce drug shortages.

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 “Patient Access to
5 Drugs in Shortage Act”.

6 **SEC. 2. IMPROVING NOTIFICATION AND REPORTING ON**
7 **DRUG SHORTAGES.**

8 (a) IN GENERAL.—

1 (1) DEFINITIONS AND NOTIFICATION.—Section
2 506C of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 356c) is amended—

4 (A) in the section heading, by striking
5 “**DISCONTINUANCE OF A LIFE SAVING**
6 **PRODUCT**” and inserting “**DISCONTINUANCE**
7 **OR INTERRUPTION OF THE MANUFACTURE**
8 **OF CERTAIN DRUGS**”; and

9 (B) by amending subsection (a) to read as
10 follows:

11 “(a) IN GENERAL.—

12 “(1) DEFINITIONS.—In this section:

13 “(A) DRUG SHORTAGE.—The term ‘drug
14 shortage’ means a period of time when patient
15 care is likely to be compromised due to the
16 available supply of a drug.

17 “(B) INTERRUPTION.—The term ‘interrup-
18 tion’, with respect to the manufacture of a
19 drug, means a change in production of the drug
20 that is likely to cause a significant shortage in
21 the supply of the drug from a manufacturer.

22 “(2) NOTIFICATIONS.—A manufacturer of a
23 drug—

24 “(A) that is—

25 “(i) life-supporting;

1 “(ii) life-sustaining;
2 “(iii) intended for use in the preven-
3 tion of a debilitating disease or condition;
4 or
5 “(iv) a sterile injectable product;
6 “(B) for which an application has been ap-
7 proved under section 505(b) or 505(j); and
8 “(C) that is not a product that was origi-
9 nally derived from human tissue and was re-
10 placed by a recombinant product,
11 shall notify the Secretary of a discontinuance or
12 interruption of the manufacture of the drug at least
13 6 months prior to the date of the discontinuance or
14 interruption.

15 “(3) EFFECT OF NOTIFICATIONS.—

16 “(A) IN GENERAL.—Except as provided in
17 subparagraph (B), a failure to take action in
18 accordance with this subsection (including a
19 failure to submit a report or a failure to provide
20 adequate information in a report submitted
21 under this section) may not be admitted as evi-
22 dence or used for any purpose in any civil ac-
23 tion in a Federal or State court or any Federal
24 or State administrative proceeding.

1 “(B) LIMITATION.—Subparagraph (A)
2 shall not apply to a civil action or administra-
3 tive proceeding brought by the United States to
4 enforce the requirements under this subsection.

5 “(C) CONSTRUCTION REGARDING OFF-
6 LABEL USE.—In no case may activities taken in
7 connection with compliance with the notification
8 requirements specified in this subsection be con-
9 strued as evidence of an intention to promote or
10 market the drug for an indication or use in a
11 manner for which the drug has not been ap-
12 proved by the Secretary.

13 “(4) EFFECT OF NONCOMPLIANCE.—If a manu-
14 facturer of a drug described in paragraph (2) fails
15 to submit a notification to the Secretary in accord-
16 ance with this subsection, then—

17 “(A) beginning on the date of such failure,
18 sections 1833(t)(14)(I), 1847A(b)(9), and
19 1927(a)(8) of the Social Security Act and sec-
20 tion 340B(f) of the Public Health Service Act
21 shall not apply to any drug manufactured by
22 such manufacturer; and

23 “(B) section 524A of this Act shall not
24 apply to such manufacturer with respect to the
25 submission of an application as described in

1 subsection (a)(1) of such section or commence-
2 ment of manufacturing of a drug as described
3 in subsection (a)(2) of such section after the
4 date of such failure.”.

5 (2) CONFORMING AMENDMENT.—Section
6 506C(b) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 356c(b)) is amended in the matter
8 preceding paragraph (1) by striking “under sub-
9 section (a)” and inserting “under subsection (a)
10 with respect to a discontinuance”.

11 (b) DISTRIBUTION; EXPEDITED REVIEWS AND IN-
12 SPECTIONS; REPORTING.—Section 506C of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amend-
14 ed—

15 (1) in subsection (c)—

16 (A) by striking “the discontinuation of the
17 drugs described in subsection (a)” and inserting
18 “discontinuations or interruptions relating to a
19 drug described in subsection (a)(2)”; and

20 (B) by adding at the end the following:
21 “Any distribution under the preceding sentence
22 shall not include any confidential commercial
23 information or trade secret.”; and

24 (2) by adding at the end the following:

1 “(d) EXPEDITED INSPECTIONS AND REVIEWS.—[To
2 be supplied.]

3 “(e) REPORTING BY OTHER ENTITIES.—The Sec-
4 retary shall establish a mechanism by which health care
5 providers and other third-party organizations may report
6 evidence of a drug shortage under this section.”.

7 (c) EFFECTIVE DATE.—The amendments made by
8 this section shall take effect on the date of enactment of
9 this Act and shall apply to discontinuances and interrup-
10 tions described under section 506C of the Federal Food,
11 Drug, and Cosmetic Act (as amended by this section) that
12 occur after the date of enactment of this Act.

13 **SEC. 3. MARKET STABILITY INCENTIVES.**

14 (a) MEDICARE.—

15 (1) IN GENERAL.—Section 1847A(b) of the So-
16 cial Security Act (42 U.S.C. 1395w–3a(b)) is
17 amended—

18 (A) in paragraph (1), in the matter pre-
19 ceding subparagraph (A), by striking “para-
20 graph (7)” and inserting “paragraphs (7) and
21 (9)”; and

22 (B) by adding at the end the following new
23 paragraph:

24 “(9) STERILE INJECTABLE PRODUCTS WITH 4
25 OR FEWER ACTIVE MANUFACTURERS.—

1 “(A) IN GENERAL.—Subject to section
2 506C(a)(4) of the Federal Food, Drug, and
3 Cosmetic Act, the payment amount for a drug
4 described in subparagraph (B) that is furnished
5 on or after January 1, 2013, and before Janu-
6 ary 1, 2020, shall be equal to—

7 “(i) in the case of a drug described in
8 subparagraph (B)(i), the amount deter-
9 mined under subparagraph (C) for the
10 drug; and

11 “(ii) in the case of a drug described in
12 subparagraph (B)(ii), the wholesale acqui-
13 sition cost (as defined in subsection (c)) of
14 the drug.

15 “(B) DRUG DESCRIBED.—A drug de-
16 scribed in this subparagraph is a sterile
17 injectable product that is manufactured by 4 or
18 fewer active manufacturers (as determined by
19 the Secretary) and is—

20 “(i) a multiple source drug (as de-
21 scribed in subsection (c)(6)(C)) for which
22 there is no period of exclusivity in effect or
23 available under section 505(j), 505A, or
24 527 of the Federal Food, Drug, and Cos-
25 metic Act; or

1 “(ii) a single source drug (as de-
2 scribed in subsection (c)(6)(D)(ii)) for
3 which there is no period of exclusivity in
4 effect or available under section 505(c),
5 505A, or 527 of the Federal Food, Drug,
6 and Cosmetic Act.

7 “(C) USE OF VOLUME-WEIGHTED AVER-
8 AGE WHOLESALE ACQUISITION COSTS FOR MUL-
9 TIPLE SOURCE DRUGS.—

10 “(i) IN GENERAL.—For all drugs de-
11 scribed in subparagraph (B) included with-
12 in the same multiple source drug billing
13 and payment code, the amount specified in
14 this subparagraph is the volume-weighted
15 average of the wholesale acquisition costs
16 reported under section 1927(b)(3)(A)(iii)
17 determined by—

18 “(I) computing the sum of the
19 products (for each National Drug
20 Code assigned to such drugs) of—

21 “(aa) the manufacturer’s
22 wholesale acquisition cost (as de-
23 fined in subsection (c)), deter-
24 mined by the Secretary without
25 dividing such cost by the total

number of billing units for the
National Drug Code for the bill-
ing and payment code; and

4 “(bb) the total number of
5 units specified under paragraph
6 (2) sold; and

7 “(II) dividing the sum deter-
8 mined under subclause (I) by the sum
9 of the products (for each National
10 Drug Code assigned to such drugs)
11 of—

12 “(aa) the total number of
13 units specified under paragraph
14 (2) sold; and

15 “(bb) the total number of
16 billing units for the National
17 Drug Code for the billing and
18 payment code.

“(ii) BILLING UNIT DEFINED.—For purposes of this subparagraph, the term ‘billing unit’ means the identifiable quantity associated with a billing and payment code, as established by the Secretary.”.

1 (2) HOPD PROSPECTIVE PAYMENT SYSTEM.—

2 Section 1833(t)(14) of the Social Security Act (42

3 U.S.C. 1395l(t)(14)) is amended—

4 (A) in subparagraph (A)(iii), in the matter
5 preceding subclause (I), by striking “subpara-
6 graph (E)” and inserting “subparagraphs (E)
7 and (I)”; and

8 (B) by adding at the end the following new
9 subparagraph:

10 “(I) STERILE INJECTABLE PRODUCTS
11 WITH 4 OR FEWER ACTIVE MANUFACTURERS.—
12 Subject to section 506C(a)(4) of the Federal
13 Food, Drug, and Cosmetic Act, the amount of
14 payment for a drug described in section
15 1847A(b)(9)(B) that is furnished on or after
16 January 1, 2013, and before January 1, 2020,
17 shall be equal to—

18 “(i) in the case of a drug described in
19 clause (i) of such section, the amount de-
20 termined under section 1847A(b)(9)(C) for
21 the drug; and

22 “(ii) in the case of a drug described in
23 clause (ii) of section 1847A(b)(9)(B), the
24 wholesale acquisition cost (as defined in
25 section 1847A(c)) of the drug.”.

1 (b) MEDICAID.—

2 (1) IN GENERAL.—Section 1927(a) of the So-
3 cial Security Act (42 U.S.C. 1396r–8(a)) is amended
4 by adding at the end the following new paragraph:

5 “(8) STERILE INJECTABLE PRODUCTS WITH 4
6 OR FEWER ACTIVE MANUFACTURERS.—

7 “(A) IN GENERAL.—Subject to section
8 506C(a)(4) of the Federal Food, Drug, and
9 Cosmetic Act, paragraph (1) of this subsection
10 and section 1903(i)(10)(A) shall not apply to a
11 drug described in subparagraph (B) that is fur-
12 nished on or after January 1, 2013, and before
13 January 1, 2020.

14 “(B) DRUG DESCRIBED.—A drug de-
15 scribed in this subparagraph is a sterile
16 injectable product that is manufactured by 4 or
17 fewer active manufacturers (as determined by
18 the Secretary) and is—

19 “(i) a multiple source drug (as de-
20 scribed in subsection (k)(7)(A)(i)) for
21 which there is no period of exclusivity in
22 effect or available under section 505(j),
23 505A, or 527 of the Federal Food, Drug,
24 and Cosmetic Act; or

1 “(ii) a single source drug (as de-
2 scribed in subsection (k)(7)(A)(iv)) for
3 which there is no period of exclusivity in
4 effect or available under section 505(c),
5 505A, or 527 of the Federal Food, Drug,
6 and Cosmetic Act.”.

7 (2) CONFORMING AMENDMENT.—Section
8 1903(i)(10)(A) of the Social Security Act (42 U.S.C.
9 1396b(i)(10)(A)) is amended by striking “unless sec-
10 tion 1927(a)(3) applies” and inserting “unless para-
11 graph (3) or (8) of section 1927(a) applies”.
12 (c) 340B PROGRAM.—

13 (1) IN GENERAL.—Section 340B of the Public
14 Health Service Act (42 U.S.C. 256b) is amended by
15 inserting after subsection (e) the following:

16 “(f) EXCLUSION OF CERTAIN STERILE INJECTABLE
17 PRODUCTS.—

18 “(1) IN GENERAL.—For purposes of this sec-
19 tion (including with respect to the prohibition de-
20 scribed in subsection (a)(5)(L)(iii)), the term ‘cov-
21 ered outpatient drug’ shall not include a drug that
22 is a sterile injectable product that is manufactured
23 by 4 or fewer active manufacturers (as determined
24 by the Secretary) and is—

1 “(A) a multiple source drug (as described
2 in section 1927(k)(7)(A)(i) of the Social Secu-
3 rity Act) for which there is no period of exclu-
4 sivity in effect or available under section 505(j),
5 505A, or 527 of the Federal Food, Drug, and
6 Cosmetic Act; or

7 “(B) a single source drug (as described in
8 section 1927(k)(7)(A)(iv) of the Social Security
9 Act) for which there is no period of exclusivity
10 in effect or available under section 505(c),
11 505A, or 527 of the Federal Food, Drug, and
12 Cosmetic Act.

13 “(2) SUNSET.—Paragraph (1) shall cease to
14 have force or effect on December 31, 2019.”.

15 (d) TRANSFER OF EXCLUSIVITY.—

16 (1) IN GENERAL.—Chapter V of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et
18 seq.) is amended by adding at the end the following:

19 **“SEC. 524A. ACTION TO ADDRESS A DRUG SHORTAGE.**

20 “(a) IN GENERAL.—Subsection (b) shall apply to a
21 sponsor or holder, as applicable, if—

22 “(1) the sponsor submits an application under
23 subsection (b) or (j) of section 505 for a drug that
24 will mitigate a shortage of a drug that is designated

1 as a drug in shortage by the Secretary as of the date
2 of such submission; or

3 “(2) the holder of an application approved
4 under subsection (b) or (j) of section 505 com-
5 mences to manufacture a drug pursuant to such ap-
6 plication that will mitigate a shortage of a drug that
7 is designated as a drug in shortage by the Secretary
8 as of the date of such commencement.

9 “(b) EFFECT OF SUBSECTION.—If a sponsor submits
10 an application described in subsection (a)(1) or a holder
11 commences manufacturing as described in subsection
12 (a)(2), the sponsor or holder may elect to extend by 5
13 years any period of exclusivity applicable under this Act
14 with respect to a drug for which the sponsor or holder
15 receives approval under section 505(b)(1) or section
16 351(a) of the Public Health Service Act after the date of
17 submission of the application described in subsection
18 (a)(1) or commencement of the manufacturing described
19 in subsection (a)(2), as applicable.

20 “(c) APPLICABILITY.—This section shall apply to—

21 “(1) sponsors that submit an application as de-
22 scribed in subsection (a)(1) before December 31,
23 2015; and

1 “(2) holders that commence manufacturing of a
2 drug as described in subsection (a)(2) before Decem-
3 ber 31, 2015.

4 “(d) EFFECT OF REMOVAL FROM DRUG SHORTAGE
5 LIST.—If, pursuant to this section, a sponsor or holder
6 extends by 5 years any exclusivity applicable under this
7 Act with respect to a drug as described under subsection
8 (b), the subsequent removal of the drug described under
9 paragraph (1) or (2) of subsection (a) from designation
10 as a drug in shortage shall have no effect on such exten-
11 sion.”.

12 (e) STUDY AND REPORT.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services shall contract with an independent
15 entity to study the effects of the amendments made
16 by this section on patient access to sterile injectable
17 products.

18 (2) REPORT.—As a condition of the contract
19 described under paragraph (1), the independent enti-
20 ty shall agree to submit to Congress and such Sec-
21 retary, not later than 3 years after the date of en-
22 actment of this Act, a report that describes the re-
23 sults of the study conducted under paragraph (1).

1 **SEC. 4. DRUG SHORTAGE LIST.**

2 Chapter V of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 351 et seq.) is amended by inserting after
4 section 506C the following:

5 **“SEC. 506D. DRUG SHORTAGE LIST.**

6 “(a) ESTABLISHMENT.—The Secretary shall main-
7 tain an up-to-date list of drugs that are verified to be in
8 shortage in the United States.

9 “(b) CONTENTS.—For each drug on such list, the
10 Secretary shall include the following information:

11 “(1) The name of the drug in shortage.

12 “(2) The name of each manufacturer of such
13 drug.

14 “(3) The reason for the shortage, as determined
15 by the Secretary, selecting from the following cat-
16 egories:

17 “(A) Requirements related to complying
18 with good manufacturing practices.

19 “(B) Regulatory delay.

20 “(C) Shortage of an active ingredient.

21 “(D) Shortage of a nonactive pharma-
22 ceutical ingredient component.

23 “(E) Discontinuation of the manufacture
24 of the drug.

25 “(F) Delay in shipping of the drug.

26 “(G) Demand increase for the drug.

1 “(4) The anticipated duration of the shortage
2 as determined by the Secretary.

3 “(c) PUBLIC AVAILABILITY.—

4 “(1) IN GENERAL.—Subject to paragraphs (2)
5 and (3), the Secretary shall make the information in
6 such list publicly available.

7 “(2) TRADE SECRETS AND CONFIDENTIAL IN-
8 FORMATION.—Nothing in this section alters or
9 amends section 1905 of title 18, United States Code,
10 or section 552(b)(4) of title 5 of such Code.

11 “(3) PUBLIC HEALTH EXCEPTION.—The Sec-
12 retary may choose not to make information collected
13 under this section publicly available under paragraph
14 (1) if the Secretary determines that disclosure of
15 such information would adversely affect the public
16 health.”.

17 **SEC. 5. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

18 Section 306 of the Controlled Substances Act (21
19 U.S.C. 826) is amended by adding at the end the fol-
20 lowing:

21 “(h)(1) Not later than 30 days after the receipt of
22 a request described in paragraph (2), the Attorney Gen-
23 eral shall—

24 “(A) complete review of such request; and

1 “(B) as necessary to address a shortage of a
2 controlled substance, increase the aggregate and in-
3 dividual production quotas under this section appli-
4 cable to such controlled substance and any ingre-
5 dient therein.

6 “(2) A request is described in this paragraph if—

7 “(A) the request pertains to a controlled sub-
8 stance on the list of drugs in shortage maintained
9 under section 506D of the Federal Food, Drug, and
10 Cosmetic Act;

11 “(B) the request is submitted by the manufac-
12 turer of the controlled substance; and

13 “(C) the controlled substance is in schedule
14 II.”.