

117TH CONGRESS
1ST SESSION

S. 2257

To provide Federal support for nonprofit generic and essential medicine and device manufacturers to increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs.

IN THE SENATE OF THE UNITED STATES

JUNE 24, 2021

Ms. ROSEN introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To provide Federal support for nonprofit generic and essential medicine and device manufacturers to increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs.

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 “Expanding Access to
5 Affordable Prescription Drugs and Medical Devices Act”.

1 **SEC. 2. SUPPORTING NONPROFIT GENERIC AND ESSENTIAL**
2 **MEDICINES AND DEVICE MANUFACTURERS.**

3 (a) IN GENERAL.—Part P of title III of the Public
4 Health Service Act (42 U.S.C. 280g et seq.) is amended
5 by adding at the end the following:

6 **“SEC. 399V-7. SUPPORTING NONPROFIT GENERIC AND ES-**
7 **SENTIAL MEDICINES AND DEVICE MANUFAC-**
8 **TURERS.**

9 “(a) IN GENERAL.—The Secretary shall award coop-
10 erative agreements and low interest revolving loans to, and
11 waive user fees with respect to, nonprofit entities to sup-
12 port the manufacture and distribution within the United
13 States of eligible drugs and eligible devices.

14 “(b) TERMS OF COOPERATIVE AGREEMENTS AND
15 LOANS.—

16 “(1) COOPERATIVE AGREEMENTS.—

17 “(A) INITIAL AWARDS.—Each cooperative
18 agreement awarded under this section shall be
19 for an initial period determined by the Sec-
20 retary, not to exceed 5 years, and shall be in an
21 amount determined by the Secretary, not to ex-
22 ceed \$5,000,000.

23 “(B) SUBSEQUENT AWARDS.—An entity
24 receiving a cooperative agreement under this
25 section may apply for additional awards with
26 respect to other eligible drugs or eligible devices

1 under this subsection. The Secretary may
2 award additional cooperative agreements to
3 such entities, for periods not to exceed 5 years,
4 in amounts not to exceed \$5,000,000.

5 “(C) EXTENSIONS.—The Secretary may
6 extend the initial time period of a cooperative
7 agreement awarded under subparagraph (A) or
8 (B), but the total award amount of the original
9 award plus any extension may not exceed
10 \$5,000,000.

11 “(2) LOW INTEREST REVOLVING LOANS.—Each
12 loan awarded under this section shall be for a period
13 determined by the Secretary, with an interest rate
14 not greater than the Federal Reserve benchmark in-
15 terest rate plus 3 percent, and in an amount not
16 greater than \$5,000,000.

17 “(c) APPLICATIONS.—

18 “(1) IN GENERAL.—To be eligible to receive a
19 cooperative agreement or loan under this section, an
20 entity shall—

21 “(A) be an organization that—

22 “(i) manufactures, or facilitates the
23 manufacture of, finished drug products or
24 devices in the United States;

1 “(ii) is an organization described in
2 paragraph (3) or (4) of section 501(c) of
3 the Internal Revenue Code of 1986 and ex-
4 empt from tax under section 501(a) of
5 such Code; and

6 “(iii) is based in the United States;

7 “(B) demonstrate expertise in the process
8 of drug or device manufacturing, and the ability
9 to fully comply with all applicable State and
10 Federal requirements;

11 “(C) agree to ensure that—

12 “(i) the highest total compensation of-
13 fered to any employee of such entity is not
14 more than 40 times greater than the total
15 compensation offered to the lowest-com-
16 pensated employee, including any self-em-
17 ployed independent contracted workers on
18 an hourly wage, of such entity;

19 “(ii) among drugs that may be self-
20 administered by patients and remaining
21 after application of clause (iii), other than
22 such drugs that are not required to be dis-
23 tributed through pharmacies—

24 “(I) the entity shall report to the
25 Secretary on an annual basis any bar-

1 riers faced in making the drug widely
2 available through retail pharmacies;
3 and

4 “(II) the entity shall, on an an-
5 nual basis and in a manner prescribed
6 by the Secretary, make publicly avail-
7 able complete information on the
8 availability of the drug from retail
9 pharmacies; and

10 “(iii) if the Secretary identifies a need
11 to supplement the strategic national stock-
12 pile under section 319F–2, the Secretary
13 has priority access to purchase, at the av-
14 erage cost price offered to other pur-
15 chasers, a quantity of the drug or device
16 equivalent to at least 25 percent of the en-
17 tity’s production, or such percentage of
18 such supply as the Secretary, in consulta-
19 tion with the entity, determines appro-
20 priate, consistent with public health needs,
21 until the need has been met;

22 “(D) include a timeline for any drugs or
23 devices manufactured by the entity that are ex-
24 pected to come to market within the duration of
25 the cooperative agreement or loan, with at least

1 one such drug or device expected to come to
2 market within 5 years of starting the coopera-
3 tive agreement or loan; and

4 “(E) submit an application at such time,
5 in such manner, and containing such additional
6 information as the Secretary may require.

7 “(2) PRIORITY.—In awarding cooperative
8 agreements and loans under this section, the Sec-
9 retary shall give priority to applications from entities
10 that are expected to manufacture and take to mar-
11 ket eligible drugs or eligible devices at a price that
12 is lower than existing treatments for the same dis-
13 ease or condition that such drug or device is in-
14 tended to treat, or to entities that are expected to
15 manufacture any eligible drug or eligible device iden-
16 tified as a public health priority by the Secretary.

17 “(3) CALCULATION OF WAGES.—For purposes
18 of paragraph (1)(C)(i) to calculate employee com-
19 pensation with respect to part-time employees, the
20 Secretary shall calculate the compensation such em-
21 ployees would receive if they were to work full-time
22 at their existing hourly wages.

23 “(4) REPORT.—The Secretary shall report to
24 Congress annually regarding barriers reported by
25 entities regarding availability of drugs described in

1 paragraph (1)(C)(ii) (other than such drugs that are
2 not required to be distributed through pharmacies)
3 through retail pharmacies and regulatory or legisla-
4 tive recommendations to improve public access to
5 such drugs.

6 “(d) DEFINITIONS.—For purposes of this section—

7 “(1) the term ‘eligible device’ means a device—

8 “(A)(i) that is approved under section 515
9 of the Federal Food, Drug, and Cosmetic Act,
10 cleared under section 510(k) of such Act, or au-
11 thorized under section 513(f)(2) of such Act;

12 “(ii) for which the device manufacturer ap-
13 plying for a cooperative agreement under sub-
14 section (a) or a low interest revolving loan
15 under subsection (b) has submitted an applica-
16 tion under section 515 of the Federal Food,
17 Drug, and Cosmetic Act, or a notification under
18 section 510(k) or 513(f)(2) of such Act; or

19 “(iii) that is urgently needed to meet a
20 public health need, as determined by the Sec-
21 retary, and for which the device manufacturer
22 applying for a cooperative agreement under
23 subsection (a) or a low interest revolving loan
24 under subsection (b) has provided a timeline for
25 submission of an application under section 515

1 of the Federal Food, Drug, and Cosmetic Act,
2 or a notification under section 510(k) or
3 513(f)(2) of such Act; and

4 “(B) that the Secretary has deemed essen-
5 tial on the basis of—

6 “(i) there being 2 or fewer active
7 manufacturers of the device or a substan-
8 tially similar device;

9 “(ii) the device having been on the de-
10 vice shortage list under section 506J(g) of
11 the Federal Food, Drug, and Cosmetic Act
12 at any time in the past 5 years;

13 “(iii) similar devices have increased in
14 cost more than the rate of inflation over
15 the most recent 5-year period;

16 “(iv) the device meeting an otherwise
17 unmet critical public health need; or

18 “(v) other factors, as determined by
19 the Secretary; and

20 “(2) the term ‘eligible drug’ means a drug—

21 “(A)(i) that is approved by the Food and
22 Drug Administration under section 505 of the
23 Federal Food, Drug, and Cosmetic Act or li-
24 censed under section 351 of this Act;

1 “(ii) for which the drug manufacturer ap-
2 plying for a cooperative agreement under sub-
3 section (a) or a low interest revolving loan
4 under subsection (b) has submitted an applica-
5 tion under subsection (b)(2) or (j) of section
6 505 of the Federal Food, Drug, and Cosmetic
7 Act or under section 351(k) of this Act; or

8 “(iii) that is urgently needed to meet a
9 public health need, as determined by the Sec-
10 retary, and for which the drug manufacturer
11 applying for a cooperative agreement under
12 subsection (a) or a low interest revolving loan
13 under subsection (b) has provided a timeline for
14 submission of an application under subsection
15 (b) or (j) of section 505 of the Federal Food,
16 Drug, and Cosmetic Act or under subsection (a)
17 or (k) of section 351 of this Act; and

18 “(B) that the Secretary has deemed essen-
19 tial on the basis of—

20 “(i) there being 2 or fewer active
21 manufacturers of the drug;

22 “(ii) the drug having been on the drug
23 shortage list under section 506E of the
24 Federal Food, Drug, and Cosmetic Act at
25 any time in the past 5 years;

1 “(iii) alternative treatments for the
2 disease or condition the drug is intended to
3 treat costing more than \$50 per 1-month
4 supply according to the public list price;

5 “(iv) the drug meeting an otherwise
6 unmet critical public health need; or

7 “(v) other purposes, as determined by
8 the Secretary.

9 “(e) USE OF FUNDS.—A recipient of an award under
10 this section may use funds for start-up, research and de-
11 velopment, or expansion costs associated with the manu-
12 facture of eligible drugs or eligible devices, in accordance
13 with the terms of the applicable cooperative agreement or
14 loan.

15 “(f) REPORT.—Not later than 3 years after the date
16 of enactment of the Expanding Access to Affordable Pre-
17 scription Drugs and Medical Devices Act and annually
18 thereafter, the Secretary shall submit a report to Congress
19 on, with respect to the applicable reporting period—

20 “(1) the number of grants and loans awarded
21 under the program;

22 “(2) the drugs and devices that came to market
23 with support from grants or loans under the pro-
24 gram;

1 “(3) a cost-savings analysis for all federally-
2 funded health programs, based on savings that were
3 realized due to a drug or device whose manufacturer
4 was supported by a grant under this section; and

5 “(4) a cost-savings analysis for consumer out-
6 of-pocket and insurance premium spending, based on
7 savings that were realized due to a drug or device
8 whose manufacturer was supported by a grant under
9 this section, and any impact on consumer access to
10 the drug or device.

11 “(g) WAIVER OF USER FEES WITH RESPECT TO EN-
12 TITIES NOT RECEIVING AN AWARD.—

13 “(1) IN GENERAL.—With respect to an entity
14 that is an organization described in paragraph (2),
15 the Secretary shall waive the following fees that
16 would otherwise be applicable during the period dur-
17 ing which such entity is so exempt and is manufac-
18 turing such product:

19 “(A) Fees under paragraphs (1) and (2) of
20 section 736(a) of the Federal Food, Drug, and
21 Cosmetic Act.

22 “(B) Fees under paragraphs (2) and (3) of
23 section 738(a) of the Federal Food, Drug, and
24 Cosmetic Act.

1 “(C) Fees under paragraphs (3), (4), and
2 (5) of section 744B(a) of the Federal Food,
3 Drug, and Cosmetic Act.

4 “(D) Fees under paragraphs (1)(A),
5 (1)(B), (2), and (3) of section 744H of the
6 Federal Food, Drug, and Cosmetic Act.

7 “(2) ENTITY DESCRIBED.—An entity described
8 in this paragraph is an entity that—

9 “(A) is described in paragraph (3) or (4)
10 of section 501(c) of the Internal Revenue Code
11 of 1986 and exempt from tax under section
12 501(a) of such Code;

13 “(B) manufactures an eligible drug or eli-
14 gible device; and

15 “(C) is not currently receiving a loan or
16 cooperative agreement under this section.

17 “(h) FUNDING.—

18 “(1) AUTHORIZATION OF APPROPRIATIONS.—
19 To carry out this section, there are authorized to be
20 appropriated such sums as may be necessary for
21 each of fiscal years 2022 through 2031.

22 “(2) LOAN REPAYMENTS.—In addition to any
23 amounts appropriated under paragraph (1), the Sec-
24 retary of the Treasury shall transfer to the Sec-
25 retary of Health and Human Services annually an

1 amount equal to the amount received for the pre-
2 vious year in payments on loans awarded under this
3 section for purposes of carrying out the program
4 under this section with respect to loans.”.

5 (b) CBO REPORT.—Not later than 1 year after the
6 date of enactment of this Act, the Director of the Congres-
7 sional Budget Office shall submit budget-neutral or cost-
8 savings policy options to Congress showing ways to cap-
9 ture the savings from nonprofit drug and device manufac-
10 turers supported by the program under section 399V–7
11 of the Public Health Service Act, as added by subsection
12 (a). Such options shall direct at least half of such savings
13 to create a mandatory funding stream to support grants
14 and low-interest loans similar to grants and loans offered
15 under section 399V–7 of the Public Health Service Act,
16 as added by subsection (a), and any remaining portion of
17 such savings toward ensuring the solvency of the Medicare
18 program under title XVIII of the Social Security Act (42
19 U.S.C. 1395 et seq.) and reducing out-of-pocket and pre-
20 mium costs under such program.

21 (c) PRIORITY REVIEW.—

22 (1) NDAs.—The Secretary of Health and
23 Human Services may grant priority review, as de-
24 scribed in the Manual of Policies and Procedures of
25 the Food and Drug Administration and goals identi-

1 fied in the letters described in section 101(b) of the
2 Prescription Drug User Fee Amendments of 2017,
3 for any application that includes a commitment to a
4 specific price that represents a significant cost re-
5 duction compared to similar treatments on the mar-
6 ket, if the sponsor is a qualified drug or device man-
7 ufacturing organization (as defined in section
8 501(s)(4) of the Internal Revenue Code of 1986).

9 (2) ANDAs.—Section 505(j)(11)(A) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 355(j)(11)(A)) is amended—

12 (A) in clause (i), by striking “; or” and in-
13 serting a semicolon;

14 (B) in clause (ii), by striking the period
15 and inserting “; or”; and

16 (C) by adding at the end the following:

17 “(iii) for which the sponsor is a qualified drug
18 or device manufacturing organization (as defined in
19 section 501(s)(4) of the Internal Revenue Code of
20 1986), and commits to a specific price that rep-
21 resents a significant cost reduction compared to
22 similar treatments on the market.”.

23 (3) BIOSIMILAR BIOLOGICAL PRODUCTS.—The
24 Secretary of Health and Human Services may grant
25 priority review for any application under section

1 351(k) of the Public Health Service Act (42 U.S.C.
2 262(k)) that includes a commitment to a specific
3 price that represents a significant cost reduction
4 compared to similar treatments on the market, if the
5 sponsor is a qualified drug or device manufacturing
6 organization (as defined in section 501(s)(4) of the
7 Internal Revenue Code of 1986).

8 (4) BREAKTHROUGH DEVICES.—Section
9 515B(b)(2) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360e–3(b)(2)) is amended—

11 (A) in subparagraph (C), by striking “; or”
12 and inserting a semicolon;

13 (B) by redesignating subparagraph (D) as
14 subparagraph (E); and

15 (C) by inserting after subparagraph (C)
16 the following:

17 “(D) for which the sponsor is a qualified drug
18 or device manufacturing organization (as defined in
19 section 501(s)(4) of the Internal Revenue Code of
20 1986), and commits to a specific price that rep-
21 resents a significant cost reduction compared to
22 similar treatments on the market; or”.

1 **SEC. 3. ADDITIONAL RULES FOR TAX-EXEMPT STATUS OF**
2 **CERTAIN DRUG AND MEDICAL DEVICE MANU-**
3 **FACTURERS.**

4 (a) IN GENERAL.—Section 501 of the Internal Rev-
5 enue Code of 1986 is amended by adding at the end the
6 following new subsection:

7 “(s) ADDITIONAL REQUIREMENTS FOR CERTAIN
8 DRUG OR MEDICAL DEVICE MANUFACTURERS.—

9 “(1) TREATMENT AS CHARITABLE ORGANIZA-
10 TION.—A qualified drug or medical device manufac-
11 turing organization shall be treated as an organiza-
12 tion organized and operated exclusively for chari-
13 table purposes under subsection (c)(3) if—

14 “(A) such organization meets the require-
15 ments under paragraph (4),

16 “(B) no part of the net earnings of such
17 organization inures to the benefit of any private
18 shareholder or individual,

19 “(C) no substantial part of the activities of
20 such organization is carrying on propaganda, or
21 otherwise attempting, to influence legislation
22 (except as otherwise provided in subsection (h)),
23 and

24 “(D) such organization does not partici-
25 pate in, or intervene in (including the pub-
26 lishing or distributing of statements), any polit-

1 ical campaign on behalf of (or in opposition to)
2 any candidate for public office.

3 “(2) TREATMENT AS SOCIAL WELFARE ORGANI-
4 ZATION.—A qualified drug or medical device organi-
5 zation shall be treated as an organization organized
6 and operated primarily to promote social welfare
7 under subsection (c)(4) if—

8 “(A) such organization meets the require-
9 ments under paragraph (4), and

10 “(B) no part of the net earnings of such
11 organization inures to the benefit of any private
12 shareholder or individual.

13 “(3) QUALIFIED DRUG OR MEDICAL DEVICE
14 MANUFACTURING ORGANIZATION.—For purposes of
15 this section—

16 “(A) IN GENERAL.—The term ‘qualified
17 drug or medical device manufacturing organiza-
18 tion’ means an organization that is organized
19 and operated exclusively for the production of
20 drugs or devices.

21 “(B) SPECIAL RULE.—An organization
22 shall not fail to be treated as a qualified drug
23 or medical device manufacturing organization
24 solely because such organization provides public
25 health education, conducts public health

1 screenings, or conducts other related charitable
2 activities.

3 “(4) REQUIREMENTS.—The requirements of
4 this paragraph are as follows:

5 “(A) ORGANIZATION AND OPERATION.—
6 The organization is organized as a nonprofit
7 corporation under State law and is compliant
8 with the laws of the State pertaining to oper-
9 ation as a pharmaceutical or medical device
10 manufacturer.

11 “(B) DRUGS AND DEVICES.—Each drug or
12 device manufactured by the organization—

13 “(i) furthers a public health objective
14 (as determined by the Secretary, in con-
15 sultation with the Secretary of Health and
16 Human Services), such as addressing bar-
17 riers related to availability, shortage, or
18 price, and

19 “(ii) meets such other requirements,
20 as determined by the Secretary, in con-
21 sultation with the Secretary of Health and
22 Human Services.

23 “(C) LIST PRICE.—

24 “(i) IN GENERAL.—The organization
25 establishes a public list price for each drug

1 or device manufactured by the organization
2 in accordance with clause (ii) and charges
3 no more than such public list price.

4 “(ii) MAXIMUM LIST PRICE.—The
5 amount of the public list price established
6 under this clause with respect to any drug
7 or device shall not be more than 120 per-
8 cent of the sum of—

9 “(I) the production costs for the
10 drug or device,

11 “(II) an amount calculated to re-
12 cover up to the previous 5 years of
13 qualified research expenses (as de-
14 fined in section 41) attributable to the
15 drug or device over a 5-year period,

16 “(III) the regulatory costs associ-
17 ated with developing and maintaining
18 a marketed drug or device,

19 “(IV) the anticipated costs (not
20 greater than the usual and customary
21 rates) of storing, warehousing, and
22 distributing the drug or device, plus

23 “(V) interest on loans directly fi-
24 nancing the development or produc-
25 tion of the drug or device.

1 “(D) COMPENSATION.—

2 “(i) IN GENERAL.—The organization
3 meets the requirements of clauses (ii), (iii),
4 and (iv).

5 “(ii) COMPENSATION AMOUNT.—

6 “(I) IN GENERAL.—The highest
7 total remuneration offered to any em-
8 ployee of the organization or of an ap-
9 plicable independent contractor of the
10 organization is not more than 40
11 times greater than the total remu-
12 nation offered to the lowest-com-
13 pensated employee of the organization
14 or of any applicable independent con-
15 tractor of the organization. For pur-
16 poses of this clause, the compensation
17 provided to a part-time hourly em-
18 ployee shall be determined by applying
19 such employee’s hourly wage to the
20 number of hours of a full-time em-
21 ployee.

22 “(II) APPLICABLE INDEPENDENT
23 CONTRACTOR.—The term ‘applicable
24 independent contractor’ means, with
25 respect to any organization, any inde-

1 pendent contractor that has less than
2 2 employees and the contract for
3 which specifies an hourly rate.

4 “(iii) COMPENSATION OF OTHER
5 INDEPENDENT CONTRACTORS.—In the
6 case of any independent contractor of the
7 organization that is not an applicable inde-
8 pendent contractor, the organization—

9 “(I) compensates any work done
10 at a fair market rate, and

11 “(II) keeps such financial infor-
12 mation as required by the Secretary
13 with respect to amounts paid to such
14 independent contractors.

15 “(iv) PROHIBITION ON OUTSIDE COM-
16 PENSATION.—The organization does not
17 permit employees to be compensated from
18 any other person for work related to the
19 organization.

20 “(E) BOARD OF DIRECTORS.—The organi-
21 zation—

22 “(i) maintains an independent board
23 of directors, and

24 “(ii) maintains a clear financial sepa-
25 ration from—

1 “(I) entities with which the orga-
2 nization conducts business, and

3 “(II) entities from which the or-
4 ganization purchases goods or serv-
5 ices.

6 “(5) OTHER DEFINITIONS.—For purposes of
7 this subsection—

8 “(A) DRUG.—The term ‘drug’ means any
9 drug that is approved under section 505 of the
10 Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 355) or licensed under section 351 of
12 the Public Health Service Act (42 U.S.C. 262).

13 “(B) DEVICE.—The term ‘device’ means
14 any device that is approved under section 515
15 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 360e), cleared under section 510(k)
17 of such Act (21 U.S.C. 360(k)), or authorized
18 under section 513(f)(2) of such Act (21 U.S.C.
19 360c(f)(2)).

20 “(6) REGULATIONS.—The Secretary shall issue
21 such regulations and guidance as may be necessary
22 to carry out the provisions of this subsection, includ-
23 ing guidance relating to determining acceptable
24 methods for making the calculation under paragraph
25 (4)(C)(ii).”.

1 (b) TREATMENT AS A PUBLIC CHARITY.—Section
2 509(a) of the Internal Revenue Code of 1986 is amended
3 by striking “and” at the end of paragraph (3), by striking
4 the period at the end of paragraph (4) and inserting “,
5 and”, and by inserting after paragraph (4) the following
6 new paragraph:

7 “(5) an organization which meets the require-
8 ments of subparagraphs (A), (B), (C), and (D) of
9 section 501(s)(1).”.

10 (c) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to taxable years beginning after
12 the date of the enactment of this Act.

13 (d) SENSE OF THE SENATE.—It is the sense of the
14 Senate that nothing in the amendments made by this sec-
15 tion shall be construed to prevent an organization that
16 manufactures drugs or medical devices and that is other-
17 wise described in paragraph (3) or (4) of section 501(c)
18 of the Internal Revenue Code of 1986 from being treated
19 as an organization that is so described.

○