II

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Expanding Access to Affordable Prescription Drugs and Medical Devices Act''.

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

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

"SEC. 399V–7. SUPPORTING NONPROFIT GENERIC AND ESSENTIAL MEDICINES AND DEVICE MANUFACTURERS.

''(a) IN GENERAL.—The Secretary shall award cooperative agreements and low interest revolving loans to, and waive user fees with respect to, nonprofit entities to support the manufacture and distribution within the United States of eligible drugs and eligible devices.

''(b) TERMS OF COOPERATIVE AGREEMENTS AND LOANS.—

''(1) COOPERATIVE AGREEMENTS.—

''(A) INITIAL AWARDS.—Each cooperative agreement awarded under this section shall be for an initial period determined by the Secretary, not to exceed 5 years, and shall be in an amount determined by the Secretary, not to exceed $5,000,000.

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

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

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

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

''(c) APPLICATIONS.—

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

''(A) be an organization that—

''(i) manufactures, or facilitates the manufacture of, finished drug products or devices in the United States;

"(ii) is an organization described in paragraph (3) or (4) of section 501(c) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code; and

"(iii) is based in the United States;

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

"(C) agree to ensure that—

"(i) the highest total compensation offered to any employee of such entity is not more than 40 times greater than the total compensation offered to the lowest-compensated employee, including any self-employed independent contracted workers on an hourly wage, of such entity;

"(ii) among drugs that may be self-administered by patients and remaining after application of clause (iii), other than such drugs that are not required to be distributed through pharmacies—

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

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

''(II) the entity shall, on an annual basis and in a manner prescribed by the Secretary, make publicly available complete information on the availability of the drug from retail pharmacies; and

''(iii) if the Secretary identifies a need to supplement the strategic national stockpile under section 319F–2, the Secretary has priority access to purchase, at the average cost price offered to other purchasers, a quantity of the drug or device equivalent to at least 25 percent of the entity's production, or such percentage of such supply as the Secretary, in consultation with the entity, determines appropriate, consistent with public health needs, until the need has been met;

''(D) include a timeline for any drugs or devices manufactured by the entity that are expected to come to market within the duration of the cooperative agreement or loan, with at least

one such drug or device expected to come to market within 5 years of starting the cooperative agreement or loan; and

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

''(2) PRIORITY.—In awarding cooperative agreements and loans under this section, the Secretary shall give priority to applications from entities that are expected to manufacture and take to market eligible drugs or eligible devices at a price that is lower than existing treatments for the same disease or condition that such drug or device is intended to treat, or to entities that are expected to manufacture any eligible drug or eligible device identified as a public health priority by the Secretary.

''(3) CALCULATION OF WAGES.—For purposes of paragraph (1)(C)(i) to calculate employee compensation with respect to part-time employees, the Secretary shall calculate the compensation such employees would receive if they were to work full-time at their existing hourly wages.

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

paragraph (1)(C)(ii) (other than such drugs that are not required to be distributed through pharmacies) through retail pharmacies and regulatory or legislative recommendations to improve public access to such drugs.

''(d) DEFINITIONS.—For purposes of this section—

''(1) the term 'eligible device' means a device—

''(A)(i) that is approved under section 515 of the Federal Food, Drug, and Cosmetic Act, cleared under section 510(k) of such Act, or authorized under section 513(f)(2) of such Act;

''(ii) for which the device manufacturer applying for a cooperative agreement under subsection (a) or a low interest revolving loan under subsection (b) has submitted an application under section 515 of the Federal Food, Drug, and Cosmetic Act, or a notification under section 510(k) or 513(f)(2) of such Act; or

''(iii) that is urgently needed to meet a public health need, as determined by the Secretary, and for which the device manufacturer applying for a cooperative agreement under subsection (a) or a low interest revolving loan under subsection (b) has provided a timeline for submission of an application under section 515

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

''(B) that the Secretary has deemed essential on the basis of—

''(i) there being 2 or fewer active manufacturers of the device or a substantially similar device;

''(ii) the device having been on the device shortage list under section 506J(g) of the Federal Food, Drug, and Cosmetic Act at any time in the past 5 years;

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

''(iv) the device meeting an otherwise unmet critical public health need; or

''(v) other factors, as determined by the Secretary; and

''(2) the term 'eligible drug' means a drug—

''(A)(i) that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

"(ii) for which the drug manufacturer applying for a cooperative agreement under subsection (a) or a low interest revolving loan under subsection (b) has submitted an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or under section 351(k) of this Act; or

"(iii) that is urgently needed to meet a public health need, as determined by the Secretary, and for which the drug manufacturer applying for a cooperative agreement under subsection (a) or a low interest revolving loan under subsection (b) has provided a timeline for submission of an application under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or under subsection (a) or (k) of section 351 of this Act; and

"(B) that the Secretary has deemed essential on the basis of—

"(i) there being 2 or fewer active manufacturers of the drug;

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

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

"(iv) the drug meeting an otherwise unmet critical public health need; or

"(v) other purposes, as determined by the Secretary.

"(e) USE OF FUNDS.—A recipient of an award under this section may use funds for start-up, research and development, or expansion costs associated with the manufacture of eligible drugs or eligible devices, in accordance with the terms of the applicable cooperative agreement or loan.

"(f) REPORT.—Not later than 3 years after the date of enactment of the Expanding Access to Affordable Prescription Drugs and Medical Devices Act and annually thereafter, the Secretary shall submit a report to Congress on, with respect to the applicable reporting period—

"(1) the number of grants and loans awarded under the program;

"(2) the drugs and devices that came to market with support from grants or loans under the program;

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

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

''(g) WAIVER OF USER FEES WITH RESPECT TO ENTITIES NOT RECEIVING AN AWARD.—

''(1) IN GENERAL.—With respect to an entity that is an organization described in paragraph (2), the Secretary shall waive the following fees that would otherwise be applicable during the period during which such entity is so exempt and is manufacturing such product:

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

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

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

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

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

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

"(B) manufactures an eligible drug or eligible device; and

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

"(h) FUNDING.—

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

"(2) LOAN REPAYMENTS.—In addition to any amounts appropriated under paragraph (1), the Secretary of the Treasury shall transfer to the Secretary of Health and Human Services annually an

amount equal to the amount received for the previous year in payments on loans awarded under this section for purposes of carrying out the program under this section with respect to loans.''.

(b) CBO REPORT.—Not later than 1 year after the date of enactment of this Act, the Director of the Congressional Budget Office shall submit budget-neutral or cost-savings policy options to Congress showing ways to capture the savings from nonprofit drug and device manufacturers supported by the program under section 399V–7 of the Public Health Service Act, as added by subsection (a). Such options shall direct at least half of such savings to create a mandatory funding stream to support grants and low-interest loans similar to grants and loans offered under section 399V–7 of the Public Health Service Act, as added by subsection (a), and any remaining portion of such savings toward ensuring the solvency of the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and reducing out-of-pocket and premium costs under such program.

(c) PRIORITY REVIEW.—

(1) NDAS.—The Secretary of Health and Human Services may grant priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identi-

fied in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017, for any application that includes a commitment to a specific price that represents a significant cost reduction compared to similar treatments on the market, if the sponsor is a qualified drug or device manufacturing organization (as defined in section 501(s)(4) of the Internal Revenue Code of 1986).

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

(A) in clause (i), by striking ''; or'' and inserting a semicolon;

(B) in clause (ii), by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) for which the sponsor is a qualified drug or device manufacturing organization (as defined in section 501(s)(4) of the Internal Revenue Code of 1986), and commits to a specific price that represents a significant cost reduction compared to similar treatments on the market.''.

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

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

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

(A) in subparagraph (C), by striking ''; or'' and inserting a semicolon;

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

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

''(D) for which the sponsor is a qualified drug or device manufacturing organization (as defined in section 501(s)(4) of the Internal Revenue Code of 1986), and commits to a specific price that represents a significant cost reduction compared to similar treatments on the market; or''.

SEC. 3. ADDITIONAL RULES FOR TAX-EXEMPT STATUS OF CERTAIN DRUG AND MEDICAL DEVICE MANUFACTURERS.

(a) IN GENERAL.—Section 501 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(s) ADDITIONAL REQUIREMENTS FOR CERTAIN DRUG OR MEDICAL DEVICE MANUFACTURERS.—

''(1) TREATMENT AS CHARITABLE ORGANIZATION.—A qualified drug or medical device manufacturing organization shall be treated as an organization organized and operated exclusively for charitable purposes under subsection (c)(3) if—

''(A) such organization meets the requirements under paragraph (4),

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

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

''(D) such organization does not participate in, or intervene in (including the publishing or distributing of statements), any polit-

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

''(2) TREATMENT AS SOCIAL WELFARE ORGANIZATION.—A qualified drug or medical device organization shall be treated as an organization organized and operated primarily to promote social welfare under subsection (c)(4) if—

''(A) such organization meets the requirements under paragraph (4), and

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

''(3) QUALIFIED DRUG OR MEDICAL DEVICE MANUFACTURING ORGANIZATION.—For purposes of this section—

''(A) IN GENERAL.—The term 'qualified drug or medical device manufacturing organization' means an organization that is organized and operated exclusively for the production of drugs or devices.

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

screenings, or conducts other related charitable activities.

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

''(A) ORGANIZATION AND OPERATION.—The organization is organized as a nonprofit corporation under State law and is compliant with the laws of the State pertaining to operation as a pharmaceutical or medical device manufacturer.

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

''(i) furthers a public health objective (as determined by the Secretary, in consultation with the Secretary of Health and Human Services), such as addressing barriers related to availability, shortage, or price, and

''(ii) meets such other requirements, as determined by the Secretary, in consultation with the Secretary of Health and Human Services.

''(C) LIST PRICE.—

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

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

''(ii) MAXIMUM LIST PRICE.—The amount of the public list price established under this clause with respect to any drug or device shall not be more than 120 percent of the sum of—

''(I) the production costs for the drug or device,

''(II) an amount calculated to recover up to the previous 5 years of qualified research expenses (as defined in section 41) attributable to the drug or device over a 5-year period,

''(III) the regulatory costs associated with developing and maintaining a marketed drug or device,

''(IV) the anticipated costs (not greater than the usual and customary rates) of storing, warehousing, and distributing the drug or device, plus

''(V) interest on loans directly financing the development or production of the drug or device.

"(D) COMPENSATION.—

"(i) IN GENERAL.—The organization meets the requirements of clauses (ii), (iii), and (iv).

"(ii) COMPENSATION AMOUNT.—

"(I) IN GENERAL.—The highest total remuneration offered to any employee of the organization or of an applicable independent contractor of the organization is not more than 40 times greater than the total remuneration offered to the lowest-compensated employee of the organization or of any applicable independent contractor of the organization. For purposes of this clause, the compensation provided to a part-time hourly employee shall be determined by applying such employee's hourly wage to the number of hours of a full-time employee.

"(II) APPLICABLE INDEPENDENT CONTRACTOR.—The term 'applicable independent contractor' means, with respect to any organization, any inde-

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

''(iii) COMPENSATION OF OTHER INDEPENDENT CONTRACTORS.—In the case of any independent contractor of the organization that is not an applicable independent contractor, the organization—

''(I) compensates any work done at a fair market rate, and

''(II) keeps such financial information as required by the Secretary with respect to amounts paid to such independent contractors.

''(iv) PROHIBITION ON OUTSIDE COMPENSATION.—The organization does not permit employees to be compensated from any other person for work related to the organization.

''(E) BOARD OF DIRECTORS.—The organization—

''(i) maintains an independent board of directors, and

''(ii) maintains a clear financial separation from—

"(I) entities with which the organization conducts business, and

"(II) entities from which the organization purchases goods or services.

"(5) OTHER DEFINITIONS.—For purposes of this subsection—

"(A) DRUG.—The term 'drug' means any drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(B) DEVICE.—The term 'device' means any device that is approved under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e), cleared under section 510(k) of such Act (21 U.S.C. 360(k)), or authorized under section 513(f)(2) of such Act (21 U.S.C. 360c(f)(2)).

"(6) REGULATIONS.—The Secretary shall issue such regulations and guidance as may be necessary to carry out the provisions of this subsection, including guidance relating to determining acceptable methods for making the calculation under paragraph (4)(C)(ii).".

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

''(5) an organization which meets the requirements of subparagraphs (A), (B), (C), and (D) of section 501(s)(1).''.

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

(d) SENSE OF THE SENATE.—It is the sense of the Senate that nothing in the amendments made by this section shall be construed to prevent an organization that manufactures drugs or medical devices and that is otherwise described in paragraph (3) or (4) of section 501(c) of the Internal Revenue Code of 1986 from being treated as an organization that is so described.

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