119TH CONGRESS
1ST SESSION

S. 3325

To amend the Internal Revenue Code of 1986 to provide rules for determining the tax-exempt status of organizations that manufacture and distribute drugs and medical devices to meet public health needs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 3, 2025

Ms. ROSEN (for herself and Mr. CURTIS) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend the Internal Revenue Code of 1986 to provide rules for determining the tax-exempt status of organizations that manufacture and distribute drugs and medical devices to meet public health needs, and for other purposes.

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 Drugs and Medical Devices Act''.

SEC. 2. TREATMENT OF PUBLIC INTEREST DRUG OR MEDICAL DEVICE HEALTH CARE ORGANIZATIONS.

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

''(s) TREATMENT OF PUBLIC INTEREST DRUG OR MEDICAL DEVICE HEALTH CARE ORGANIZATIONS.—

''(1) IN GENERAL.—An organization that has been designated as a public interest drug or medical device health care organization under this subsection shall not fail to be treated as an organization described in subsection (c)(3) solely because such organization, either directly or by contract, manufactures or distributes drugs or medical devices in a manner consistent with its designation under this subsection.

''(2) ELIGIBILITY FOR DESIGNATION.—

''(A) IN GENERAL.—The Secretary may designate an organization that, either directly or by contract, manufactures or distributes drugs or medical devices as a public interest drug or medical device health care organization under this subsection if the Secretary, in consultation with the Secretary of Health and Human Services, determines that—

''(i) the primary purpose of such organization is making eligible drugs or medical devices affordable,

''(ii) such organization is created or organized in the United States and primarily operated in the United States,

''(iii) such organization is not controlled by a person which is not exempt from tax under section 501(a), and

''(iv) such organization meets the organizational requirements of subparagraph (B).

''(B) ORGANIZATIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An organization meets the requirements of this subparagraph if—

''(I) no more than the applicable number of members of the board the organization is also a board member or executive staff member of a disqualified entity, and

''(II) no executive staff member of the organization is also a board member or executive staff member of a disqualified entity.

"(ii) APPLICABLE NUMBER.—For purposes of subparagraph (B)(i), the applicable number is—

"(I) in the case of an organization with less than 3 board members, zero, and

"(II) in the case of any other organization, 1.

"(iii) EXCEPTION FOR WHOLLY OWNED SUBSIDIARIES.—An organization shall not be treated as failing to meet the requirements of clause (i) with respect to any board member or executive staff member of the organization if—

"(I) the disqualified entity is a wholly owned subsidiary of the organization, and

"(II) the board member or executive staff member serves a similar role with respect to such wholly owned subsidiary.

"(iv) EXCEPTION IF NO BUSINESS TRANSACTION.—Clause (i)(II) shall not apply if the organization and the disquali-

fied entity are prohibited from engaging in business transactions with each other.

''(C) DISQUALIFIED ENTITY.—For purposes of subparagraph (B), the term 'disqualified entity' means, with respect to any organization described in subparagraph (B)(i), any person which—

''(i) is in the trade or business of manufacturing or distributing drugs or medical devices, and

''(ii) is not exempt from tax under section 501(a).

''(3) ELIGIBLE DRUG OR MEDICAL DEVICE.—

''(A) IN GENERAL.—For purposes of this section, the term 'eligible drug or medical device' means any drug or medical device if the Secretary (in consultation with the Secretary of Health and Human Services) determines that such drug or medical device—

''(i) meets the requirements of either clause (i) or (ii) of subparagraph (B); and

''(ii) meets the requirements of at least one other clause of such subparagraph.

''(B) REQUIREMENTS.—The requirements of this subparagraph with respect to any drug or medical device are as follows:

''(i) The drug or medical device is in shortage (as defined in, as applicable, section 506C(h) or section 506J(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(h); 356j(j)), or, with respect to an over-the-counter drug, as determined by the Secretary of Health and Human Services), nationwide or in a part of the United States (determined through geographic area or population group), or is at risk of such shortage.

''(ii) The manufacture or distribution of the drug or medical device is expected to significantly reduce—

''(I) the cost of such drug or device for patients directly or indirectly (which may be determined through savings to the Medicare plan under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Medicaid program under title XIX of such

Act (42 U.S.C. 1396 et seq.), or within the health system), or

"(II) in the case of a novel drug or device, reduce the costs compared to current standard of care (which may be determined by taking into account reduced hospitalizations and other medically related expenses or price in comparison to other available products with similar approved uses).

"(iii) The manufacture or distribution of the drug or medical device is expected to address a currently unmet health need.

"(iv) The manufacture or distribution of the drug is expected to address a public health need identified by the Secretary (in consultation with the Secretary of Health and Human Services), or to address supply needs for drugs and devices used during public health or other national emergencies.

"(4) REQUEST FOR DESIGNATION.—An organization may request to be designated as a public interest drug or medical device health care organiza-

tion under this subsection by submitting to the Secretary the following:

"(A) Evidence that the manufacturer or distributor currently has, or has plans to develop, the ability to manufacture or distribute a drug or medical device which is an eligible drug or medical device.

"(B) An agreement that, in the event that the Secretary of Health and Human Services identifies a need to supplement the strategic national stockpile with a drug or medical device designated under this subsection, the manufacturer or distributor will give the Secretary priority access to purchase such drug or device, at a cost that is not more than the average cost price offered to other purchasers, in a quantity that is equivalent to at least 25 percent of the manufacturer's production or the distributor's stock at the time of the request for designation, until the need identified by the Secretary has been met.

Nothing in an agreement under subparagraph (B) shall be construed to prohibit an organization from supplying the identified drug or medical device to any other person at the time or in the manner as

required under a contract entered into before the date such drug or device is identified by the Secretary under subparagraph (B).

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

''(A) DRUG.—The term 'drug' means a drug 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. 252).

''(B) MEDICAL DEVICE.—The term 'medical device' has the meaning given the term 'device' in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

''(6) REGULATIONS AND GUIDANCE.—The Secretary (in consultation with the Secretary of Health and Human Services) shall issue such regulations or other guidance as is necessary to carry out the purposes of this subsection, including regulations or other guidance—

''(A) establishing affordability guidelines and cost transparency requirements for purposes of determining whether an organization meets the requirements of paragraph (2)(A) with respect to any eligible drug or medical de-

vice, including taking into account the sustainability of operations, capital expenditures, research and development, and maintenance of reasonable reserves,

''(B) determining what constitutes an unmet health need for purposes of paragraph (3)(B)(iii), and

''(C) for monitoring the continued compliance of the requirements of this subsection for organizations designated as public interest drug or medical device health care organizations.''.

(b) EXCESS BENEFITS.—

(1) IN GENERAL.—Section 4958(f)(1) of the Internal Revenue Code of 1986 is amended by striking ''and'' at the end of subparagraph (E), by striking the period at the end of subparagraph (F) and inserting '', and'', and by adding at the end the following new subparagraph:

''(G) which involves public interest drug or medical device health care organization (within the meaning of section 501(s)), any person who provides funding to such organization which is not permissible funding.''.

(2) PERMISSIBLE FUNDING.—Section 4958(f) of such Code is amended by adding at the end the following new paragraph:

''(9) PERMISSIBLE FUNDING.—For purposes of paragraph (1)(G), the term 'permissible funding' means funding from—

''(A) amounts which do not exceed 1 percent of the gross receipts of such organization for the taxable year of the organization in which such amount is received,

''(B) amounts received pursuant to grants from or contracts with any governmental entity or organization which is exempt from tax under section 501(a), or

''(C) amounts provided in connection with the purchase of drugs or medical devices (other than purchases from any disqualified entity (as defined in section 501(s)(2)(C))).''.

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

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