

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

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.

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 Drugs and Medical Devices Act”.

1 **SEC. 2. TREATMENT OF PUBLIC INTEREST DRUG OR MED-**
 2 **ICAL DEVICE HEALTH CARE ORGANIZATIONS.**

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

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

8 “(1) IN GENERAL.—An organization that has
 9 been designated as a public interest drug or medical
 10 device health care organization under this subsection
 11 shall not fail to be treated as an organization de-
 12 scribed in subsection (c)(3) solely because such orga-
 13 nization, either directly or by contract, manufactures
 14 or distributes drugs or medical devices in a manner
 15 consistent with its designation under this subsection.

16 “(2) ELIGIBILITY FOR DESIGNATION.—

17 “(A) IN GENERAL.—The Secretary may
 18 designate an organization that, either directly
 19 or by contract, manufactures or distributes
 20 drugs or medical devices as a public interest
 21 drug or medical device health care organization
 22 under this subsection if the Secretary, in con-
 23 sultation with the Secretary of Health and
 24 Human Services, determines that—

1 “(i) the primary purpose of such orga-
2 nization is making eligible drugs or med-
3 ical devices affordable,

4 “(ii) such organization is created or
5 organized in the United States and pri-
6 marily operated in the United States,

7 “(iii) such organization is not con-
8 trolled by a person which is not exempt
9 from tax under section 501(a), and

10 “(iv) such organization meets the or-
11 ganizational requirements of subparagraph
12 (B).

13 “(B) ORGANIZATIONAL REQUIREMENTS.—

14 “(i) IN GENERAL.—An organization
15 meets the requirements of this subpara-
16 graph if—

17 “(I) no more than the applicable
18 number of members of the board the
19 organization is also a board member
20 or executive staff member of a dis-
21 qualified entity, and

22 “(II) no executive staff member
23 of the organization is also a board
24 member or executive staff member of
25 a disqualified entity.

1 “(ii) APPLICABLE NUMBER.—For pur-
2 poses of subparagraph (B)(i), the applica-
3 ble number is—

4 “(I) in the case of an organiza-
5 tion with less than 3 board members,
6 zero, and

7 “(II) in the case of any other or-
8 ganization, 1.

9 “(iii) EXCEPTION FOR WHOLLY
10 OWNED SUBSIDIARIES.—An organization
11 shall not be treated as failing to meet the
12 requirements of clause (i) with respect to
13 any board member or executive staff mem-
14 ber of the organization if—

15 “(I) the disqualified entity is a
16 wholly owned subsidiary of the organi-
17 zation, and

18 “(II) the board member or execu-
19 tive staff member serves a similar role
20 with respect to such wholly owned
21 subsidiary.

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

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

3 “(C) DISQUALIFIED ENTITY.—For pur-
4 poses of subparagraph (B), the term ‘disquali-
5 fied entity’ means, with respect to any organi-
6 zation described in subparagraph (B)(i), any
7 person which—

8 “(i) is in the trade or business of
9 manufacturing or distributing drugs or
10 medical devices, and

11 “(ii) is not exempt from tax under
12 section 501(a).

13 “(3) ELIGIBLE DRUG OR MEDICAL DEVICE.—

14 “(A) IN GENERAL.—For purposes of this
15 section, the term ‘eligible drug or medical de-
16 vice’ means any drug or medical device if the
17 Secretary (in consultation with the Secretary of
18 Health and Human Services) determines that
19 such drug or medical device—

20 “(i) meets the requirements of either
21 clause (i) or (ii) of subparagraph (B); and

22 “(ii) meets the requirements of at
23 least one other clause of such subpara-
24 graph.

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

4 “(i) The drug or medical device is in
5 shortage (as defined in, as applicable, sec-
6 tion 506C(h) or section 506J(j) of the
7 Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 356c(h); 356j(j)), or, with respect
9 to an over-the-counter drug, as determined
10 by the Secretary of Health and Human
11 Services), nationwide or in a part of the
12 United States (determined through geo-
13 graphic area or population group), or is at
14 risk of such shortage.

15 “(ii) The manufacture or distribution
16 of the drug or medical device is expected to
17 significantly reduce—

18 “(I) the cost of such drug or de-
19 vice for patients directly or indirectly
20 (which may be determined through
21 savings to the Medicare plan under
22 title XVIII of the Social Security Act
23 (42 U.S.C. 1395 et seq.), the Med-
24 icaid program under title XIX of such

1 Act (42 U.S.C. 1396 et seq.), or with-
2 in the health system), or

3 “(II) in the case of a novel drug
4 or device, reduce the costs compared
5 to current standard of care (which
6 may be determined by taking into ac-
7 count reduced hospitalizations and
8 other medically related expenses or
9 price in comparison to other available
10 products with similar approved uses).

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

14 “(iv) The manufacture or distribution
15 of the drug is expected to address a public
16 health need identified by the Secretary (in
17 consultation with the Secretary of Health
18 and Human Services), or to address supply
19 needs for drugs and devices used during
20 public health or other national emer-
21 gencies.

22 “(4) REQUEST FOR DESIGNATION.—An organi-
23 zation may request to be designated as a public in-
24 terest drug or medical device health care organiza-

1 tion under this subsection by submitting to the Sec-
2 retary the following:

3 “(A) Evidence that the manufacturer or
4 distributor currently has, or has plans to de-
5 velop, the ability to manufacture or distribute a
6 drug or medical device which is an eligible drug
7 or medical device.

8 “(B) An agreement that, in the event that
9 the Secretary of Health and Human Services
10 identifies a need to supplement the strategic na-
11 tional stockpile with a drug or medical device
12 designated under this subsection, the manufac-
13 turer or distributor will give the Secretary pri-
14 ority access to purchase such drug or device, at
15 a cost that is not more than the average cost
16 price offered to other purchasers, in a quantity
17 that is equivalent to at least 25 percent of the
18 manufacturer’s production or the distributor’s
19 stock at the time of the request for designation,
20 until the need identified by the Secretary has
21 been met.

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

1 required under a contract entered into before the
 2 date such drug or device is identified by the Sec-
 3 retary under subparagraph (B).

4 “(5) DEFINITIONS.—For purposes of this sec-
 5 tion—

6 “(A) DRUG.—The term ‘drug’ means a
 7 drug approved under section 505 of the Federal
 8 Food, Drug, and Cosmetic Act (21 U.S.C. 355)
 9 or licensed under section 351 of the Public
 10 Health Service Act (42 U.S.C. 252).

11 “(B) MEDICAL DEVICE.—The term ‘med-
 12 ical device’ has the meaning given the term ‘de-
 13 vice’ in section 201(h) of the Federal Food,
 14 Drug, and Cosmetic Act (21 U.S.C. 321(h)).

15 “(6) REGULATIONS AND GUIDANCE.—The Sec-
 16 retary (in consultation with the Secretary of Health
 17 and Human Services) shall issue such regulations or
 18 other guidance as is necessary to carry out the pur-
 19 poses of this subsection, including regulations or
 20 other guidance—

21 “(A) establishing affordability guidelines
 22 and cost transparency requirements for pur-
 23 poses of determining whether an organization
 24 meets the requirements of paragraph (2)(A)
 25 with respect to any eligible drug or medical de-

1 vice, including taking into account the sustain-
 2 ability of operations, capital expenditures, re-
 3 search and development, and maintenance of
 4 reasonable reserves,

5 “(B) determining what constitutes an
 6 unmet health need for purposes of paragraph
 7 (3)(B)(iii), and

8 “(C) for monitoring the continued compli-
 9 ance of the requirements of this subsection for
 10 organizations designated as public interest drug
 11 or medical device health care organizations.”.

12 (b) EXCESS BENEFITS.—

13 (1) IN GENERAL.—Section 4958(f)(1) of the In-
 14 ternal Revenue Code of 1986 is amended by striking
 15 “and” at the end of subparagraph (E), by striking
 16 the period at the end of subparagraph (F) and in-
 17 serting “, and”, and by adding at the end the fol-
 18 lowing new subparagraph:

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

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

4 “(9) PERMISSIBLE FUNDING.—For purposes of
 5 paragraph (1)(G), the term ‘permissible funding’
 6 means funding from—

7 “(A) amounts which do not exceed 1 per-
 8 cent of the gross receipts of such organization
 9 for the taxable year of the organization in
 10 which such amount is received,

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

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

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

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