

118TH CONGRESS
1ST SESSION

H. R. 5486

To protect and expand access to pasteurized, donor human milk, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 14, 2023

Ms. HOULAHAN (for herself, Mrs. BICE, Ms. SALAZAR, Ms. MACE, and Mrs. LESKO) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To protect and expand access to pasteurized, donor human milk, 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 “Access to Donor Milk
5 Act of 2023”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

1 (1) The term “donor human milk” means
2 human milk that is collected, pasteurized, and dis-
3 pensed without additives.

4 (2) The term “donor human milk bank” means
5 an organization that—

6 (A) meets standards established by the
7 Food and Drug Administration for purposes of
8 ensuring the safety of donor human milk and
9 human milk banks; and

10 (B) collects, tests, processes, pasteurizes,
11 and distributes donor human milk, in compli-
12 ance with applicable law.

13 (3) The term “nonprofit donor human milk
14 bank” means a donor human milk bank (as defined
15 in paragraph (2)) that is an organization described
16 in section 501(c)(3) of the Internal Revenue Code of
17 1986 (26 U.S.C. 501(c)(3)) and exempt from tax
18 under section 501(a) of such Code (26 U.S.C.
19 501(a)).

20 **SEC. 3. SUPPORT FOR DONOR HUMAN MILK ACTIVITIES.**

21 Section 17 of the Child Nutrition Act of 1966 (42
22 U.S.C. 1786) is amended—

23 (1) in subsection (b)(4), by inserting “(includ-
24 ing support for donor human milk (as defined in

1 section 2 of the Access to Donor Milk Act of 2023)
2 activities)” after “promotion”; and

3 (2) in subsection (h)(1)(C)—

4 (A) in clause (i), by striking “clause (ii)”
5 and inserting “clauses (ii) and (iii)”; and

6 (B) by adding at the end the following:

7 “(iii) DONOR HUMAN MILK.—A State
8 agency may use amounts made available
9 under clause (i) for—

10 “(I) collecting and storing dona-
11 tions of unprocessed human milk; and

12 “(II) the transfer of the milk de-
13 scribed in subclause (I) to a nonprofit
14 donor human milk bank (as defined in
15 section 2 of the Access to Donor Milk
16 Act of 2023) registered with the Food
17 and Drug Administration.”.

18 **SEC. 4. EMERGENCY CAPACITY FUNDING FOR HUMAN MILK**

19 **BANKS.**

20 (a) IN GENERAL.—The Secretary of Health and
21 Human Services (referred to in this section as the “Sec-
22 retary”) shall award competitive grants, subject to sub-
23 section (f), to eligible entities for expanding emergency ca-
24 pacity with respect to banking donor human milk.

1 (b) APPLICATION.—An eligible entity seeking a grant
2 under this section shall submit an application to the Sec-
3 retary at such time, in such manner, and containing such
4 information as the Secretary may require.

5 (c) USE OF FUNDS.— Expanding emergency capacity
6 pursuant to a grant under this section may include—

7 (1) publicizing the need for donor human milk,
8 especially for high-risk infants;

9 (2) raising awareness and providing resources
10 to families, especially families of high-risk infants,
11 about donor human milk;

12 (3) covering donor human milk collection, stor-
13 age, pasteurization, transfer, and processing fees;

14 (4) increasing staffing and supplies needed at
15 donor human milk banks;

16 (5) purchasing consumable products needed for
17 donor human milk processing; and

18 (6) acquiring equipment for safe and quality
19 processing of donor human milk.

20 (d) ELIGIBLE ENTITY.—For purposes of this section,
21 the term “eligible entity” means an entity that—

22 (1) is a nonprofit donor human milk bank reg-
23 istered with the Food and Drug Administration; and

1 (2) in the application submitted under sub-
2 section (b), demonstrates, with respect to such enti-
3 ty—

4 (A) a rapid increase in demand for donor
5 human milk; or

6 (B) a shortage of supplies needed to oper-
7 ate a donor human milk bank.

8 (e) AUTHORIZATION OF APPROPRIATIONS.—For the
9 purposes of carrying out this section, there are authorized
10 to be appropriated \$3,000,000 for fiscal year 2024, and
11 such sums as may be necessary for each fiscal year there-
12 after.

13 (f) CRITERIA.—The Secretary may award grants
14 under subsection (a) only in the event of any of the fol-
15 lowing:

16 (1) The Secretary determines that expanded ca-
17 pacity is necessary to respond to any major disaster
18 declared by the President under section 401 of the
19 Robert T. Stafford Disaster Relief and Emergency
20 Assistance Act (42 U.S.C. 5170) or to any public
21 health emergency declared under section 319 of the
22 Public Health Service Act (42 U.S.C. 247d).

23 (2) The Secretary determines that Federal as-
24 sistance is needed to supplement State and local ef-
25 forts and capabilities to save lives and to protect

1 property and public health and safety, or to lessen
2 or avert the threat of a catastrophe in any part of
3 the United States.

4 (3) The Secretary determines emergency capac-
5 ity is needed to ensure adequate supply is available
6 to meet the demand for donor human milk from an
7 eligible entity.

8 **SEC. 5. PUBLIC AWARENESS CAMPAIGN WITH RESPECT TO**
9 **DONOR HUMAN MILK.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services—

12 (1) shall, acting through the Administrator of
13 the Health Resources and Services Administration,
14 develop a public awareness campaign with respect to
15 the benefits and safety of donor human milk from
16 donor human milk banks registered with the Food
17 and Drug Administration; and

18 (2) is encouraged to work with nonprofit donor
19 human milk banks registered with the Food and
20 Drug Administration.

21 (b) DISTRIBUTION OF EDUCATIONAL MATERIALS.—
22 The public awareness campaign under subsection (a) shall
23 include the distribution of educational materials to—

24 (1) clinicians, such as pediatric specialists, pedi-
25 atricians, obstetricians, pediatric nutritionists, mid-

1 wives, and lactation consultants, including inter-
2 national board-certified lactation consultants;

3 (2) expectant and new parents, with a focus on
4 expectant and new parents that are participating in
5 the special supplemental nutrition program for
6 women, infants, and children program under section
7 17 of the Child Nutrition Act of 1966 (42 U.S.C.
8 1786); and

9 (3) community-based organizations.

10 **SEC. 6. REGULATORY STATUS OF DONOR HUMAN MILK.**

11 (a) PUBLIC MEETING.—Not later than 180 days
12 after the date of the enactment of this Act, the Secretary
13 of Health and Human Services (referred to in this section
14 as the “Secretary”) shall convene a public meeting to in-
15 form the draft guidance required under subsection (b).

16 (b) GUIDANCE.—Not later than 18 months after the
17 date of enactment of this Act, the Secretary shall issue
18 draft guidance that—

19 (1) addresses the appropriate standards for the
20 collection and preparation, storage, handling, proc-
21 esses used in pasteurization, and transfer of donor
22 human milk and donor human-milk derived prod-
23 ucts; and

- 1 (2) considers the appropriateness of screening
- 2 and other processes, as determined by the Secretary.

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