

AMENDMENTS TO HOUSE BILL NO. 1001

Sponsor: SENATOR BROOKS

Printer's No. 1126

1 Amend Bill, page 3, line 2, by inserting after "the"

2 donor

3 Amend Bill, page 3, lines 5 through 8, by striking out all of

4 said lines

5 Amend Bill, page 3, lines 15 through 18, by striking out all

6 of said lines

7 Amend Bill, page 3, line 28, by striking out "5(a)" and

8 inserting

9 5(a)(6)

10 Amend Bill, page 4, line 5, by striking out "or" and

11 inserting a comma

12 Amend Bill, page 4, line 6, by inserting after "facility"

13 or directly to an outpatient

14 Amend Bill, page 4, line 8, by striking out "A" and inserting

15 Subject to the provisions of section 10, a

16 Amend Bill, page 4, line 13, by striking out "Human" and

17 inserting

18 Subject to the provisions of section 10, human

19 Amend Bill, page 4, line 14, by inserting after "donated"

20 without remuneration

21 Amend Bill, page 4, lines 16 and 17, by striking out all of

22 said lines

23 Amend Bill, page 5, line 20, by striking out "The term

1 includes HMBANA."

2 Amend Bill, page 6, line 10, by striking out "7" and
3 inserting

4 7(d)

5 Amend Bill, page 6, lines 12 through 14, by striking out all
6 of lines 12 and 13 and "(ii)" in line 14 and inserting

7 (i)

8 Amend Bill, page 6, line 16, by striking out the period after
9 "banks" and inserting

10 ; or

11 Amend Bill, page 6, line 17, by striking out "(iii)" and
12 inserting

13 (ii)

14 Amend Bill, page 6, line 17, by inserting after "Is"

15 otherwise

16 Amend Bill, page 6, line 19, by striking out all of said line
17 and inserting

18 (c) Initial inspection.--

19 (1) Prior to the issuance of a license,

20 Amend Bill, page 6, by inserting between lines 21 and 22

21 (2) Notwithstanding the requirement of paragraph (1),
22 the department need not inspect the facility if:

23 (i) the facility has a valid license or
24 accreditation from another state and the department is
25 satisfied that the other state's license addresses
26 appropriate health and safety concerns; or

27 (ii) the facility is registered and in good standing
28 with the United States Food and Drug Administration, and
29 the department has received confirmation that the
30 facility has satisfactorily addressed all observations
31 raised in previous inspections.

32 Amend Bill, page 6, lines 23 through 25, by striking out all
33 of lines 23 and 24 and "(2)" in line 25 and inserting

34 (1)

35 Amend Bill, page 6, line 29, by striking out "(3)" and

1 inserting

2 (2)

3 Amend Bill, page 6, line 29, by striking out "which is
4 denied" and inserting

5 that is denied a license

6 Amend Bill, page 7, lines 1 and 2, by striking out "or within
7 30 days of the deemed denial if no written explanation is
8 received"

9 Amend Bill, page 7, line 17, by striking out "7" and
10 inserting

11 7(h)

12 Amend Bill, page 7, line 19, by striking out "Written" and
13 inserting

14 The department shall provide written

15 Amend Bill, page 7, line 21, by inserting after "revocation"
16 of a license

17 Amend Bill, page 7, line 24, by striking out "its
18 application" and inserting

19 the milk bank's application or pending decision on whether
20 the exemption specified in section 10 applies

21 Amend Bill, page 8, by inserting between lines 5 and 6

22 (2) No donor milk or donor-milk-derived product may be
23 distributed by a milk bank without:

24 (i) testing to address associated risks as
25 identified by the guidelines of the milk bank under
26 section 7(c); and

27 (ii) otherwise satisfying the provisions of section
28 6.

29 Amend Bill, page 8, line 6, by striking out "(2)" and
30 inserting

31 (3)

32 Amend Bill, page 8, by inserting between lines 8 and 9

33 (4) A board of directors or similar body shall oversee
34 the milk bank's operating, regulatory and compliance efforts

1 and the work of the managing director, the medical director
2 and the medical advisory committee.

3 (5) A milk bank shall have a medical director who is a
4 licensed physician with a minimum of four years' experience
5 in neonatology, pediatrics, blood banking, infectious disease
6 or a related field.

7 Amend Bill, page 8, line 9, by striking out "(3)" and
8 inserting

9 (6)

10 Amend Bill, page 8, lines 16 through 24, by striking out all
11 of said lines

12 Amend Bill, page 8, line 25, by striking out "Each licensed
13 milk bank" and inserting

14 A licensee

15 Amend Bill, page 8, line 27, by striking out "at the milk
16 bank"

17 Amend Bill, page 9, line 27, by striking out "licensed milk
18 bank" and inserting

19 licensee

20 Amend Bill, page 9, line 30, by striking out "licensed milk
21 bank" and inserting

22 licensee

23 Amend Bill, page 10, lines 9 through 15, by striking out all
24 of said lines and inserting

25 (2) Provide consent for the milk bank to contact:

26 (i) The potential donor's health care providers and
27 medically screen and blood test the potential donor to
28 ensure the health of the potential donor and to ensure
29 the donor milk is free of any chemical, disease or
30 substance that could injure an infant receiving the milk.

31 (ii) The health care providers of the donor's
32 biological baby to verify that the baby is achieving
33 adequate growth, except in cases of bereavement,
34 surrogacy or adoption.

35 Amend Bill, page 11, line 5, by inserting after "Holder"

36 and vat

1 Amend Bill, page 11, line 13, by striking out the period
2 after "collection" and inserting
3 or the bar code that supplies the information required
4 under this paragraph.

5 Amend Bill, page 13, line 24, by striking out all of said
6 line and inserting

7 (e) Inspection of facilities and documentation.--The
8 following shall apply:

9 (1) The

10 Amend Bill, page 13, by inserting between lines 29 and 30

11 (2) Notwithstanding the requirement of paragraph (1),
12 the department need not inspect the facility if:

13 (i) the facility has a valid license or
14 accreditation from another state and the department is
15 satisfied that the other state's license addresses
16 appropriate health and safety concerns;

17 (ii) the facility is registered and in good standing
18 with the United States Food and Drug Administration, and
19 the department has received confirmation that the
20 facility has satisfactorily addressed all observations
21 raised in previous inspections.

22 Amend Bill, page 14, line 28, by striking out "person" and
23 inserting

24 milk bank

25 Amend Bill, page 14, lines 29 and 30, by striking out "an
26 entity" and inserting

27 a milk bank

28 Amend Bill, page 14, line 30, by striking out "9(c)" and
29 inserting

30 10

31 Amend Bill, page 14, by inserting after line 30

32 (4) The sale or distribution of donor milk or any donor-
33 milk-derived product in violation of section 5(a)(2).

34 Amend Bill, page 15, line 12, by striking out "approved" and
35 inserting

36 accredited

1 Amend Bill, page 15, lines 12 and 13, by striking out ", if
2 necessary," and inserting
3 approved
4 Amend Bill, page 15, by inserting between lines 13 and 14
5 Section 10. Exemptions.
6 Amend Bill, page 15, line 14, by striking out "(c) Donor
7 remuneration" and inserting
8 (a) General rule
9 Amend Bill, page 15, line 16, by inserting after "provide"
10 donor
11 Amend Bill, page 15, line 17, by inserting after
12 "voluntarily"
13 and
14 Amend Bill, page 15, lines 17 through 28, by striking out
15 "determining whether to grant" in line 17 and all of lines 18
16 through 28 and inserting
17 order to be granted this exemption, the milk bank must
18 satisfy the following:
19 (1) The milk bank may not sell, donate or distribute
20 donor milk and donor-milk-derived products for which the
21 donor has been remunerated without testing for controlled
22 substances as determined by the department. The department
23 may, at any time, require additional testing for donor milk
24 and donor-milk-derived products.
25 (2) The milk bank may not sell, donate or distribute
26 donor milk and donor-milk-derived products for which the
27 donor has been remunerated without obtaining medical
28 verification that the donor's biological infant is achieving
29 adequate growth.
30 (3) The milk bank must meet or exceed any additional
31 standards required by the department reasonably necessary to
32 protect public health and the recipient of the donor milk,
33 the donor and the donor's baby.
34 (b) Construction.--If the milk bank is exempt under
35 subsection (a), the donor of the human milk shall be considered
36 a "donor" as defined in section 3 and the human milk provided by
37 the donor shall be considered "donor milk" as defined in section
38 3.
39 (c) Penalties.--A violation of this section shall constitute
40 a misdemeanor of the third degree.

1 (d) Applicability.--The provisions of subsection (a)(1) and
2 (2) shall not apply to milk banks that do not remunerate donors.

3 Amend Bill, page 15, line 29, by striking out "10" and
4 inserting

5 11

6 Amend Bill, page 16, lines 19 through 28, by striking out all
7 of said lines and inserting

8 Section 12. Licensure application.

9 Upon the effective date of this section, the department shall
10 create an application for the licensure of milk banks. The
11 department shall begin accepting applications for licensure of
12 milk banks 120 days after the effective date of this section.

13 Section 13. Regulations.

14 The department may promulgate rules and regulations to
15 administer and enforce this act.

16 Amend Bill, page 16, line 29, by striking out "12" and
17 inserting

18 14

19 Amend Bill, page 17, lines 1 and 2, by striking out all of
20 said lines and inserting

21 (1) The following provisions shall take effect
22 immediately:

23 (i) This section.

24 (ii) Section 12.

25 (iii) Section 13.