

## 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.