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**By: Chairman, Environmental Matters Committee (Departmental - Health and Mental Hygiene)**

Introduced and read first time: February 14, 1996

Assigned to: Environmental Matters

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A BILL ENTITLED

1 AN ACT concerning

2 **Tissue Banks**

3 FOR the purpose of making technical revisions to the law governing the operation of  
4 tissue banks and tissue bank services; defining certain terms; clarifying the authority  
5 of the Secretary of Health and Mental Hygiene over certain tissue banks; clarifying  
6 the authority of the Secretary to set certain fees; modifying the manner in which  
7 certain licenses are renewed; and generally relating to the regulation of tissue banks  
8 by the Secretary of Health and Mental Hygiene.

9 BY repealing and reenacting, with amendments,

10 Article - Health - General  
11 Section 17-301, 17-302, 17-303, 17-304, 17-305, 17-306, 17-307, 17-308, 17-310,  
12 17-311, 17-312, and 17-313  
13 Annotated Code of Maryland  
14 (1994 Replacement Volume and 1995 Supplement)

15 BY repealing

16 Article - Health - General  
17 Section 17-309  
18 Annotated Code of Maryland  
19 (1994 Replacement Volume and 1995 Supplement)

20 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
21 MARYLAND, That the Laws of Maryland read as follows:

22 **Article - Health - General**

23 17-301.

24 (a) In this subtitle the following words have the meanings indicated.

25 (b) "[Permit] LICENSE" means a permit OR OTHER DOCUMENT issued by the  
26 Secretary GRANTING APPROVAL OR AUTHORITY TO:

27 (1) [To operate a] OFFER OR PERFORM tissue bank SERVICES in this  
28 State; [or]

2

1 (2) [To represent] REPRESENT or service in this State a tissue bank [that  
2 is outside this State] REGARDLESS OF THE TISSUE BANK'S LOCATION; OR

3 (3) OFFER OR PERFORM TISSUE BANK SERVICES AT A TISSUE BANK  
4 LOCATED OUTSIDE THIS STATE WHEN THE TISSUE IS INTENDED FOR USE IN THIS  
5 STATE.

6 (c) [(1)] "Tissue bank" means an ENTITY, SITE, FACILITY, OR establishment that  
7 obtains, COLLECTS, ACQUIRES, stores, processes, distributes, ALLOCATES, or sells  
8 human blood or other human tissue for use in the human body.

9 [(2) "Tissue bank" includes a blood bank.]

10 (D) "TISSUE BANK SERVICES" MEANS ANY ACTIVITY RELATING TO HUMAN  
11 TISSUE FOR USE IN THE HUMAN BODY INCLUDING OBTAINING, COLLECTING,  
12 ACQUIRING, STORING, PROCESSING, DISTRIBUTING, ALLOCATING, OR SELLING ANY  
13 KIND OF HUMAN TISSUE.

14 (E) "TISSUE" MEANS A GROUP OR COLLECTION OF CELLS AND  
15 INTERCELLULAR MATERIAL REGARDED AS AN ENTITY THAT ACTS COLLECTIVELY  
16 IN THE PERFORMANCE OF A PARTICULAR FUNCTION IN A HUMAN BODY.

17 17-302.

18 (a) (1) The Secretary shall adopt rules and regulations that set standards AND  
19 REQUIREMENTS for tissue banks.

20 (2) The rules and regulations shall contain the standards AND  
21 REQUIREMENTS that the Secretary considers necessary to assure the citizens of this  
22 State that tissue banks provide safe and reliable services.

23 (b) To assure compliance with the standards AND REQUIREMENTS IN THIS  
24 SUBTITLE AND IN REGULATIONS adopted under this subtitle, the Secretary shall:

25 (1) [Have] CONDUCT an inspection [made] of each tissue bank for which  
26 a [permit] LICENSE to operate is sought; and

27 (2) [Have] CONDUCT an inspection [made] periodically [or make an  
28 agreement with an organization to do, at no cost to this State, a periodic inspection] of  
29 each tissue bank for which a [permit] LICENSE has been issued.

30 (C) (1) A TISSUE BANK ACCREDITED BY AN ORGANIZATION APPROVED BY  
31 THE SECRETARY SHALL BE DEEMED TO MEET THE:

32 (I) STATE'S INSPECTION REQUIREMENTS UNDER SUBSECTION  
33 (B)(2) OF THIS SECTION; OR

34 (II) STATE'S STANDARDS UNDER THIS SUBTITLE IF THE  
35 SECRETARY DETERMINES THE STANDARDS OF THE ACCREDITING ORGANIZATION  
36 EQUIVALENT TO THE STATE'S REQUIREMENTS.

37 (2) THE TISSUE BANK SHALL SUBMIT THE REPORT OF THE  
38 ACCREDITING ORGANIZATION TO THE SECRETARY WITHIN 30 DAYS OF ITS RECEIPT.

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1 (3) THE SECRETARY MAY INSPECT A TISSUE BANK ACCREDITED BY AN  
2 ORGANIZATION FOR THE PURPOSE OF A COMPLAINT INVESTIGATION OR TO  
3 VALIDATE FINDINGS OF THE ACCREDITING ORGANIZATION.

4 17-303.

5 (a) The Secretary shall adopt rules and regulations that set qualifications for  
6 directors AND OTHER PERSONNEL of tissue banks.

7 (b) The rules and regulations shall require that a tissue bank [in this State]  
8 employ or retain under contract:

9 (1) A technical director, [qualified by] WITH APPROPRIATE training and  
10 experience [for] IN the scope [of activities being pursued] AND CLASSES OF TISSUE  
11 BANK SERVICES PROVIDED, who will oversee and be responsible for all technical aspects  
12 of the tissue bank's operations; and

13 (2) A medical director who [will be] IS a physician licensed to practice  
14 medicine in this State [and] OR THE STATE WHERE THE TISSUE BANK IS LOCATED,  
15 who will be responsible for all medical aspects of the tissue bank's operations, unless the  
16 technical director qualifies as a medical director under this section.

17 (C) AN INDIVIDUAL MAY BE BOTH THE TECHNICAL DIRECTOR AND THE  
18 MEDICAL DIRECTOR IF THE INDIVIDUAL MEETS THE QUALIFICATION  
19 REQUIREMENTS OF SUBSECTION (B)(1) AND (2) OF THIS SECTION.

20 17-304.

21 The Secretary shall set reasonable LICENSING fees [for the issuance and renewal of  
22 permits].

23 17-305.

24 A person shall hold a [permit] LICENSE issued by the Secretary before the person  
25 may:

26 (1) [Operate a] OFFER OR PERFORM tissue bank SERVICES in this State;  
27 [or]

28 (2) Represent or service in this State [any] A tissue bank [that is outside  
29 this State] REGARDLESS OF THE TISSUE BANK'S LOCATION; OR

30 (3) OFFER OR PERFORM TISSUE BANK SERVICES AT A TISSUE BANK  
31 LOCATED OUTSIDE THIS STATE WHEN THE TISSUE IS INTENDED FOR USE IN THIS  
32 STATE.

33 17-306.

34 To qualify for a [permit] LICENSE, an applicant shall PROVIDE EVIDENCE TO  
35 satisfy the Secretary that the tissue bank [to be operated, represented, or serviced] and  
36 its [director] PERSONNEL meet the STANDARDS AND requirements [that the Secretary  
37 adopts under] IN THIS SUBTITLE AND IN REGULATIONS ADOPTED PURSUANT TO this  
38 subtitle.

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1 17-307.

2 (a) An applicant for a [permit] LICENSE shall submit an application to the  
3 Secretary on the form that the Secretary requires.

4 (b) [(1)] An application for a [permit] LICENSE to operate a tissue bank shall  
5 include THE:

6 (1) NAME OF THE TISSUE BANK;

7 (2) NAMES OF THE DIRECTORS;

8 [(i)] (3) [The name] NAME of the owner;

9 [(ii)] (4) [The classes] CLASSES of TISSUE BANK services that the  
10 tissue bank would provide; [and]

11 (5) KINDS OF TISSUE THAT THE TISSUE BANK WOULD PROVIDE; AND

12 [(iii)] (6) Any other information that the Secretary requires.

13 [(2) An application for a permit to represent or service a tissue bank shall  
14 include satisfactory evidence that the tissue bank to be represented or serviced and its  
15 director meet the requirements that the Secretary adopts under this subtitle.]

16 (c) The applicant shall pay to the Department the application fee set by the  
17 Secretary.

18 17-308.

19 (a) The Secretary shall issue a [permit] LICENSE to any applicant who meets the  
20 STANDARDS AND requirements of this subtitle AND IN REGULATIONS ADOPTED  
21 PURSUANT TO THIS SUBTITLE.

22 (b) [The Secretary shall include on each permit that the Secretary issues] A  
23 TISSUE BANK LICENSE SHALL INCLUDE THE NAME OF THE:

24 (1) [The name of the tissue] TISSUE bank;

25 (2) [The name of its] MEDICAL director; AND

26 (3) [The name of its owner] OWNER OF THE TISSUE BANK[; and

27 (4) The classes of services that the tissue bank may offer].

28 (C) A TISSUE BANK LICENSE SHALL DESIGNATE THE:

29 (1) CLASSES OF TISSUE BANK SERVICES THAT THE TISSUE BANK MAY  
30 OFFER OR PERFORM;

31 (2) KINDS OF TISSUES THE TISSUE BANK MAY PROVIDE; OR

32 (3) A COMBINATION OF ITEMS (1) AND (2) OF THIS SUBSECTION.

33 (D) A TISSUE BANK MAY NOT BE OPERATED IN ANY MANNER BEYOND WHAT  
34 IS DESIGNATED BY ITS LICENSE.

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1 (E) A TISSUE BANK LICENSE ISSUED BY THE SECRETARY UNDER THIS  
2 SUBTITLE IS NOT TRANSFERABLE.

3 [17-309.

4 While it is effective, a permit authorizes the permit holder:

5 (1) To operate or to represent or service the tissue bank named in the  
6 permit; and

7 (2) To offer and perform the classes of services set forth in the permit.]

8 17-310.

9 (a) A [permit] LICENSE expires on the [first anniversary of its effective] date  
10 SET BY THE SECRETARY, unless the [permit] LICENSE is renewed [for a 1-year term]  
11 as provided in this section.

12 [(b) At least 1 month before the permit expires, the Department shall send to the  
13 permit holder, by first class mail to the last known address of the holder, a renewal notice  
14 that states:

15 (1) The date on which the current permit expires;

16 (2) The date by which the renewal application must be received by the  
17 Secretary for the renewal to be issued and mailed before the permit expires; and

18 (3) The amount of the renewal fee.]

19 [(c)] (B) Before the [permit] LICENSE expires, the [permit holder periodically]  
20 LICENSEE may renew [it] ITS LICENSE for an additional [1-year] term, if the [permit  
21 holder] LICENSEE:

22 [(1) Otherwise is entitled to the permit;]

23 [(2)] (1) Pays to the Department the renewal fee set by the Secretary; and

24 [(3)] (2) Submits to the Secretary:

25 (i) A renewal application on the form that the Secretary requires; and

26 (ii) Satisfactory evidence of compliance with [any] ALL THE  
27 standards and [qualifications set] REQUIREMENTS under this subtitle [for permit  
28 renewal] AND IN REGULATIONS ADOPTED PURSUANT TO THIS SUBTITLE.

29 [(d)] (C) The Secretary shall renew [the permit] LICENSE of each [permit  
30 holder] LICENSEE who meets the requirements of this section.

31 17-311.

32 (a) The Secretary may deny a [permit] LICENSE to any applicant or suspend or  
33 revoke a [permit or the authority to offer or perform any class of service that the permit  
34 sets forth,] LICENSE if the tissue bank or its [director fails] PERSONNEL FAIL to meet  
35 the STANDARDS AND requirements [that the Secretary adopts under] UNDER THIS  
36 SUBTITLE AND IN REGULATIONS ADOPTED PURSUANT TO this subtitle.

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1 (B) IF THE SECRETARY FINDS THAT A TISSUE BANK ISSUED A LICENSE  
2 UNDER THIS SUBTITLE NO LONGER MEETS THE STANDARDS AND REQUIREMENTS  
3 OF THIS SUBTITLE AND IN REGULATIONS ADOPTED UNDER THIS SUBTITLE, THE  
4 SECRETARY MAY IN LIEU OF SUSPENDING OR REVOKING THE LICENSE, IMPOSE A  
5 DIRECTED PLAN OF CORRECTION OR LIMIT THE AUTHORITY TO OFFER OR  
6 PERFORM ANY CLASS OF TISSUE BANK SERVICE THAT THE LICENSE AUTHORIZES.

7 [(b)] (C) Except as otherwise provided in the Administrative Procedure Act,  
8 before the Secretary [takes any action] DENIES, SUSPENDS OR REVOKES A LICENSE  
9 under this section, the Secretary shall give the applicant or [permit holder] LICENSEE  
10 notice and an opportunity for a hearing.

11 17-312.

12 [(a) A person may not operate a tissue bank in this State unless the] UNLESS A  
13 person holds a [permit] LICENSE issued by the Secretary, THE PERSON MAYNOT:

14 (1) OFFER OR PERFORM TISSUE BANK SERVICES IN THIS STATE;

15 (2) REPRESENT OR SERVICE IN THIS STATE, A TISSUE BANK  
16 REGARDLESS OF THE TISSUE BANK'S LOCATION; OR

17 (3) OFFER OR PERFORM TISSUE BANK SERVICES AT A TISSUE BANK  
18 LOCATED OUTSIDE THIS STATE WHEN THE TISSUE IS INTENDED FOR USE IN THIS  
19 STATE.

20 [(b) A permit holder may not offer or perform any class of service of a tissue bank  
21 that is not authorized by the permit.]

22 17-313.

23 [(a) A person may not represent or service any tissue bank, regardless of location,  
24 unless the] UNLESS A tissue bank [and its director meet the standards and qualifications  
25 that the Secretary adopts under this subtitle] HAS A LICENSE, NO OTHER PERSON ON  
26 ITS BEHALF MAY:

27 (1) OFFER OR PERFORM ANY CLASS OF TISSUE BANK SERVICES IN THIS  
28 STATE;

29 (2) REPRESENT OR SERVICE IN THIS STATE, THE TISSUE BANK  
30 REGARDLESS OF THE TISSUE BANK'S LOCATION; OR

31 (3) OFFER OR PERFORM TISSUE BANK SERVICES AT THE TISSUE BANK  
32 LOCATED OUTSIDE THIS STATE WHEN THE TISSUE IS INTENDED FOR USE IN THIS  
33 STATE.

34 [(b) A person may not represent or service in this State any tissue bank that is not  
35 in this State unless the person holds a permit to represent or service the tissue bank.]

36 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
37 October 1, 1996.