
By: Chairman, Finance Committee (Departmental - Health and Mental Hygiene)

Requested: October 16, 1996

Introduced and read first time: January 8, 1997

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Laboratories - Tissue Banks**

3 FOR the purpose of making technical revisions to the law governing tissue banks;
4 clarifying the authority of the Secretary of Health and Mental Hygiene over tissue
5 banks; defining certain terms; and generally relating to the regulation of tissue
6 banks.

7 BY repealing and reenacting, with amendments,
8 Article - Health - General
9 Section 17-301 through 17-308 and 17-310 through 17-314
10 Annotated Code of Maryland
11 (1994 Replacement Volume and 1996 Supplement)

12 BY repealing
13 Article - Health - General
14 Section 17-309
15 Annotated Code of Maryland
16 (1994 Replacement Volume and 1996 Supplement)

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

19 **Article - Health - General**

20 17-301.

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

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

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

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

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

4 (C) "TISSUE" MEANS A GROUP OR COLLECTION OF CELLS AND
5 INTERCELLULAR MATERIAL REGARDED AS AN ENTITY THAT ACTS COLLECTIVELY
6 IN THE PERFORMANCE OF A PARTICULAR FUNCTION IN A HUMAN BODY.

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

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

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

15 17-302.

16 (a) (1) The Secretary shall adopt [rules and] regulations that set standards
17 AND REQUIREMENTS for tissue banks.

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

21 (b) To assure compliance with the standards AND REQUIREMENTS IN THIS
22 SUBTITLE AND IN REGULATIONS adopted [under] PURSUANT TO this subtitle, the
23 Secretary shall:

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

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

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

31 (I) INSPECTION REQUIREMENTS UNDER SUBSECTION (B)(2) OF
32 THIS SECTION; AND

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

36 (2) THE TISSUE BANK SHALL SUBMIT THE REPORT OF THE
37 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 THE directors of tissue banks.

7 (b) (1) The [rules and] regulations shall require that a tissue bank [in this
8 State] employ or retain under contract:

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

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

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

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 MEDICAL AND TECHNICAL [director] DIRECTORS meet the STANDARDS AND
37 requirements IN THIS SUBTITLE AND IN REGULATIONS [that the Secretary adopts
38 under] ADOPTED PURSUANT TO this 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] 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:

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

31 (2) THE 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.] 17-309.

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] REQUIREMENTS [set] under this subtitle AND IN
28 REGULATIONS ADOPTED PURSUANT TO THIS SUBTITLE [for permit renewal].

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.] 17-310.

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 to meet the STANDARDS AND
35 requirements UNDER THIS SUBTITLE AND [that the Secretary adopts under] IN
36 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 PURSUANT TO THIS SUBTITLE,
4 THE SECRETARY MAY IMPOSE A DIRECTED PLAN OF CORRECTION OR LIMIT THE
5 AUTHORITY TO OFFER OR PERFORM ANY CLASS OF TISSUE BANK SERVICE THAT
6 THE LICENSE AUTHORIZES, IN LIEU OF SUSPENDING OR REVOKING THE LICENSE.

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.] 17-311.

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 MAY NOT:

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] LICENSEE may not offer or perform any class of service of
21 a tissue bank that is not authorized by the [permit] LICENSE.

22 [17-313.] 17-312.

23 [(a) A person may not represent or service any tissue bank, regardless of location,
24 unless the] UNLESS A tissue bank HAS A LICENSE [and its director meet the standards
25 and qualifications that the Secretary adopts under this subtitle], 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 [17-314.] 17-313.

37 A person who violates any provision of this subtitle is guilty of a misdemeanor and
38 on conviction is subject to a fine not exceeding \$100 for the first offense and not

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1 exceeding \$500 for each subsequent conviction for a violation of the same provision. Each
2 day a violation is continued after the first conviction is a subsequent offense.

3 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
4 October 1, 1997.