

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2009

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HOUSE DRH80132-SQ-20 (03/09)

Short Title: Tissue Bank Accreditation.

(Public)

Sponsors: Representative Allen.

Referred to:

1 A BILL TO BE ENTITLED
2 AN ACT TO REQUIRE CERTAIN TISSUE BANKS OPERATING IN NORTH CAROLINA
3 TO BE ACCREDITED BY THE AMERICAN ASSOCIATION OF TISSUE BANKS OR
4 THE EYE BANK ASSOCIATION OF AMERICA.

5 The General Assembly of North Carolina enacts:

6 **SECTION 1.** Chapter 131E of the General Statutes is amended by adding a new
7 Article to read:

8 "Article 8A.

9 "Regulation of Tissue Banks.

10 "**§ 131E-171. Registration and accreditation requirements.**

11 (a) Any tissue bank that recovers human tissue at a location outside of a hospital, when
12 such tissue is intended for human transplantation, shall be registered with the Food and Drug
13 Administration and accredited by either the American Association of Tissue Banks (AATB), or
14 accredited by the Eye Bank Association of America (EBAA), unless the establishment is an
15 organ procurement organization that has been designated by the federal Secretary for Health
16 and Human Services and is registered with the Food and Drug Administration as a tissue bank.

17 (b) For purposes of this Article, 'human tissue' means musculoskeletal tissue, including
18 bone, tendons, ligaments, fascia, cartilage, and related soft tissues, skin, cardiac tissue, dura
19 mater, and ocular tissue. Human tissue in this Article shall not include oocytes, semen,
20 embryos, or stem cells from peripheral blood or umbilical cord blood sources.

21 "**§ 131E-172. Inspection, enforcement, penalties.**

22 (a) The Department is authorized to inspect the records of any tissue bank engaged in
23 the recovery of human tissue for human transplantation in the State to ascertain compliance
24 with the registration and accreditation requirements of this Article.

25 (b) Notwithstanding the existence or pursuit of any other remedy, the Department may
26 maintain an action in the name of the State for injunctive relief or other process against any
27 tissue bank to restrain or prevent recovery of human tissue for human transplantation without
28 the required registration or accreditation or otherwise restrain or prevent substantial
29 noncompliance with this Article or the rules adopted pursuant to it.

30 (c) If any person hinders the proper performance of duty of the Department in carrying
31 out the provisions of this Article, the Department may institute an action in the superior court
32 of the county in which the hindrance occurred for injunctive relief against the continued
33 hindrance.

34 (d) Any person who knowingly and willfully engages in the recovery of human tissue
35 for human transplantation without registration with the Food and Drug Administration or



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1 accreditation by the AATB or EBAA as required by this Article is guilty of a Class 3
2 misdemeanor and upon conviction is liable only for a fine of not more than five hundred dollars
3 (\$500.00) for the first offense and not more than five hundred dollars (\$500.00) for each
4 subsequent offense."

5 **SECTION 2.** This act becomes effective October 1, 2009, and applies to tissue
6 banks engaged in the recovery of human tissue or cells for human transplantation on or after
7 that date.